UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL RESEARCH SERVICE

ANIMAL INSPECTION AND QUARANTINE BRANCH

RULES AND REGULATIONS

Relating to Viruses, Serums, Toxins, and Analogous Products, and to Certain Organisms and Vectors

Edition of November 1954

UNITED STATES DEPARTMENT OF AGRICULTURE

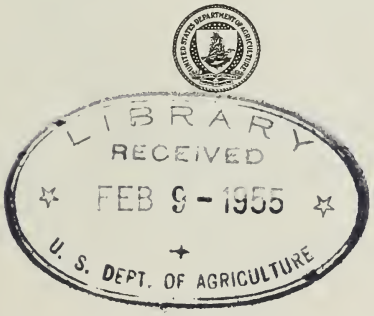
AGRICULTURAL RESEARCH SERVICE

ANIMAL INSPECTION AND QUARANTINE BRANCH

RULES AND REGULATIONS

Relating to Viruses, Serums, Toxins, and Analogous Products, and to Certain Organisms and Vectors

Edition of November 1954



UNITED STATES
GOVERNMENT PRINTING OFFICE
WASHINGTON : 1954

CONTENTS

CODE OF FEDERAL REGULATIONS OF THE UNITED STATES DEPARTMENT OF AGRICULTURE

Title 9—Animals and Animal Products

CHAPTER I—AGRICULTURAL RESEARCH SERVICE, DEPARTMENT OF AGRICULTURE

Subchapter E—Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors

PART 101—GENERAL PROVISIONS

§ 101.1 **Definitions.** The following words, when used in the regulations in Parts 101 through 122 of this subchapter, shall be construed, respectively, to mean:

(a) **Virus-Serum-Toxin Act.** The act of Congress of March 4, 1913, 37 Stat. 832–833, 21 U. S. C. 151–158.

(b) **Regulations.** The provisions in Parts 101 through 122 of this subchapter.

(c) **Biological products.** All viruses, serums, toxins, and analogous products, such as antitoxins, vaccines, tuberculins, malleins, live microorganisms, killed microorganisms, and products of microorganisms, intended for use in the treatment of domestic animals, including the diagnosis or detection of diseases of such animals.

(d) **Organisms.** All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry).

(e) **Vectors.** All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

(f) **Domestic animals.** Domestic animals, including poultry.

(g) **Department.** The United States Department of Agriculture.

(h) **Secretary.** The Secretary of the Department or any officer or employee of the Department to whom authority has heretofore lawfully been delegated, or may hereafter lawfully be delegated, to act in his stead.

(i) **Branch.** The Animal Inspection and Quarantine Branch of the Department.

(j) **Chief.** The Chief of the Branch or any officer or employee of the Branch to whom authority has heretofore lawfully been delegated, or may hereafter lawfully be delegated, to act in his stead.

(m) **Inspector.** Any officer or employee of the Branch who is authorized by the Chief to do any inspection work of the Branch.

(n) **Veterinary inspector.** A graduate of a veterinary college accredited by the Civil Service Commission, who is duly appointed and assigned for duty in the Branch as a veterinary virus-serum inspector or veterinarian.

(o) **Virus-serum inspector.** A layman appointed and trained to assist a veterinary inspector in the performance of his duties.

(p) **Person.** Any individual, firm, partnership, corporation, company, society, association, or other organized group, of any of the foregoing, or any agent, officer, or employee of any thereof.

(q) **Licensed establishment.** An establishment operated by a person holding an unexpired, unsuspended, and unrevoked license issued by the Secretary for the preparation of any biological product under the regulations.

(r) **Licensee.** A person to whom a license to manufacture biological products has been issued under the regulations.

(s) **Permittee.** A person to whom a permit to import or transport biological products or organisms or vectors has been issued under the regulations.

(t) **Official station.** One or more licensed establishments included under a single supervisory unit.

(u) **Inspector in charge.** The veterinary inspector who is assigned by the Chief to supervise and perform official work at an official station and who reports directly to the Chief.

(v) **Veterinary inspection.** An examination made by a veterinary inspector, assisted as needed by a virus-serum inspector, to determine the fitness of animals, establishments,

facilities, and procedures used in connection with the preparation of biological products under the regulations.

(w) **Hog-cholera virus.** The clear serum, plasma, or defibrinated blood derived from pigs sick of hog cholera and free from other communicable disease or diseases.

(x) **Hyperimmunizing virus.** Virus prepared for injecting into immune hogs in the production of anti-hog-cholera serum.

(y) **Inoculating virus.** Virus prepared for injecting into pigs in the production of hog-cholera virus.

(z) **Simultaneous virus.** Virus prepared for injection along with anti-hog-cholera serum in the immunization of hogs against hog cholera.

(aa) **Anti-hog-cholera serum.** The clear serum, plasma, or other derivatives of hyperimmune blood containing the protective substances derived from immune hogs which have been hyperimmunized by intravenous injection with hog-cholera virus. Such serum shall consist of not less than 88 percent of true serum and not more than 12 percent of such solutions as are required for clarification of the blood and preservation of the serum. The completed product shall represent not more than 83 percent of the defibrinated hyperimmune blood or not more than 80.51 percent of the whole hyperimmune blood used in its preparation.

(bb) **Immediate or true container.** The unit, bottle, vial, ampul, tube, or other receptacle in which any biological product is customarily distributed.

(cc) **Batch.** The quantity of a biological product thoroughly mixed in a single container and properly identified. (For special definition of "batch" as used in § 119.23, see § 119.23 (a) (10) of this chapter.)

(dd) **Serial number.** The number given each batch of a biological product by the manufacturer to identify the batch with his records of production thereof.

(ee) **Expiration date.** The date placed upon labels affixed to or used in connection with immediate or true containers of biological products by manufacturers thereof to indicate the limit of time during which the manufacturer estimates said products will retain their full strength or potency, when properly stored and handled.

(ff) **"U. S. Released."** Term used in marking a biological product to show that it has been prepared and tested in accordance with the regulations and has been found not to be worthless, contaminated, dangerous, or harmful.

(gg) **Day.** Time elapsing between any regular working hour of one day and any regular working hour of the following day.

(hh) **"Branch lock."** A Branch lock or seal or both as the inspector in charge may require.

See also other definitions in § 119.23 of this chapter.

PART 102—LICENSES AND PERMITS TO IMPORT BIOLOGICAL PRODUCTS

LICENSES

IMPORT PERMITS FOR BIOLOGICAL PRODUCTS

SUSPENSION OR REVOCATION OF LICENSES AND PERMITS; NOTICES RE DANGEROUS PRODUCTS

ASSIGNMENT OF INSPECTORS AND FACILITIES

LICENSES

§ **102.1 Licenses required.** Every person operating an establishment in the United States in which any biological product is prepared for sale, barter, or exchange in the District of Columbia or in any Territory of, or place under the jurisdiction of, the United States, or for shipment or delivery for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, shall hold an unexpired, unsuspended, and unrevoked license issued by the Secretary, and shall have inspection as provided by the regulations.

§ 102.2 Biological products; preparing and handling. All biological products produced in each licensed establishment shall be prepared, handled, stored, marked, received for transportation, and transported as required by the regulations.

§ 102.3 License application. (a) The operator of each establishment of the kind specified in § 102.1 shall make application in writing to the Secretary for a license. When a person conducts more than one establishment, a separate application shall be made for a license for each establishment. Whenever subsidiaries are to operate in an establishment for which license application is made, the applicant shall apply for permission for such subsidiaries to operate in the establishment and furnish therewith a complete statement regarding the relationship between the applicant and the subsidiaries. Blank forms of application will be furnished upon request to the Animal Inspection and Quarantine Branch, U. S. Department of Agriculture, Washington, D. C.

(b) Triplicate copies of plans, properly drawn to scale, and of specifications, including plumbing, drainage, and sewage disposal of establishments, together with information regarding all claims to be made on labels and in advertising matter to be used in connection with or relating to all biological products prepared therein, shall accompany the application for a license, unless such plans, specifications, and information have already been furnished.

(c) In case of change of ownership, operation, or location of an establishment while an application is pending, or after a license has been issued, a new application shall be made.

§ 102.4 Licenses; issuance, number, and form. (a) Before a license will be issued by the Secretary for any establishment, an inspection shall be made to determine whether the condition, equipment, facilities, and the like, of the establishment, and its methods of preparing, handling, and storing biological products are in conformity with the requirements of the regulations. A license will not be issued unless (1) in the opinion of the Chief, the condition of the establishment and the methods of preparation of biological products are such as reasonably to insure that the products will accomplish the object for which they are intended, and that they are not worthless, contaminated, dangerous, or harmful, (2) the establishment is to be operated under the direct supervision of a person competent, in the opinion of

the Chief, by education and experience, to handle all matters pertaining to the disease involved and the preparation and testing of the biological products named in the application, and (3) written assurance is filed with the Branch that the products for which the license is to be issued will not be so advertised as to mislead or deceive the purchaser and that the packages or containers in which the same are to be marketed will not bear any statement, design, or device which is false or misleading in any particular.

(b) Licenses shall be numbered and shall be in the following form:

UNITED STATES VETERINARY LICENSE NO. _____

BIOLOGICAL PRODUCTS

Washington, D. C., _____

This is to certify that, pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, _____ is hereby licensed to maintain at _____ an establishment for the preparation of _____.

This license is subject to termination as provided in the regulations made under the authority contained in said act, and to suspension or revocation if the licensee violates or fails to comply with said act or the regulations made thereunder.

_____

Secretary of Agriculture

Countersigned:

_____

Chief, Animal Inspection and Quarantine Branch

(c) Two or more licenses may bear the same number when they are issued for establishments under the same ownership or control, provided a serial letter is added in each case to identify each license and the products produced thereunder.

(d) When a license is issued for an establishment it shall not apply to more than one person at the same location, except that subsidiaries of the licensee, when named in the license, may operate thereunder at the establishment named. The licensee with its subsidiaries will be held responsible for all operations conducted in the licensed establishment.

(e) As of November 1 of each year or whenever requested by the Chief, each licensee shall submit, through the office of the inspector in charge, a list of biological products with all their forms which are to be continued in production.

Should the licensee discontinue production of some of the biological products named in his licenses, he shall return to the Branch for termination all outstanding licenses covering such products, with a list of products with all their forms which he will continue to produce. Whenever a number of licenses issued at different times are outstanding they shall be returned to the Chief at his request for consolidation.

(f) Every license outstanding on the effective date of the regulations which is in conflict therewith shall be returned for termination, with an application for a new license.

§ 102.5 Biological products; preparation by another licensee. No biological products authorized to be prepared in a licensed establishment shall be prepared in whole or in part by any other licensed establishment unless authorized in advance by the Chief.

§ 102.6 Separation of establishments. Each licensed establishment shall be separate and distinct from any unlicensed establishment in which any biological product is prepared or handled.

§ 102.7 Special licenses. (a) Special licenses may be issued in particular cases for preparation of a biological product when, in the opinion of the Chief, the laboratory and other research data and other information available with respect to the product show that the product has value in the treatment of domestic animals but that the results of its use under a larger variety of conditions should be further evaluated prior to release under a regular license. A special license for such a product may include any or all of the following requirements as may be prescribed by the Chief to protect the livestock industry or other segments of the public:

(1) The product shall be prepared under Branch inspection and tested in such manner as may be administratively determined by the Chief.

(2) The applicant for a license shall currently file with the Chief a statement of the substance of all claims proposed to be made for the product at any time while the product is under special license, and the product shall be recommended for use only under such conditions as the Chief deems warranted by the laboratory and other research data and other information currently available concerning it.

(3) Where the nature of the product so requires for the protection of the public, the product shall be recommended for use only by trained personnel.

(4) No change shall be made in the composition or method of preparation of the product without prior approval of the Chief.

(5) The licensee shall distribute the product in any State or other jurisdiction only in accordance with the requirements of such State or other jurisdiction.

(6) The licensee shall request the handlers to whom he distributes the product to (i) keep complete records showing the name and address of each purchaser of the product and the name, serial number, and quantity of the product sold to such purchaser; (ii) furnish to each veterinarian, animal owner, or other person using the product, a report form, approved by the Branch, which shall contain blank spaces for stating pertinent information concerning the results obtained from use of the product; and (iii) request users of the product to complete and return the report form to an official of the Department specified by the Chief.

(b) Special licenses may include such other requirements as the Chief may impose to protect the livestock industry and other segments of the public when the Chief finds that adequate protection thereof will not be afforded by the requirements set forth in paragraph (a) of this section.

(c) Notice of all requirements to be imposed under paragraph (a) or paragraph (b) of this section shall be given to the applicant for license for any product under the act as soon as possible after it is determined that such product may be licensed only under special license, and the applicant shall be afforded an opportunity to present his views with respect to such requirements.

(d) Each applicant for a special license shall furnish all information required by other provisions of the regulations in this subchapter, and all provisions of such regulations in terms applicable to a product for which a special license has been or is to be issued shall apply to such product, except insofar as such provisions are inconsistent with any requirement under this section.

(e) Each applicant for a special license shall agree to distribute the product to be covered by the license only for such use as may be authorized under the license.

(f) Violation of any of the conditions of a special license shall constitute a violation of this section and may be grounds for suspension or revocation of the special license under § 102.51.

(g) Special licenses shall be converted to regular licenses as soon as field data and other available information justify the change.

§ 102.8 Instructions to licensee; products not prepared under license. When a license is issued, the inspector in charge shall furnish the licensee with a copy of the regulations. If the licensee, at the time the license is issued, has in the establishment any biological products which have not theretofore been prepared, and the containers of which have not theretofore been marked, in compliance with the regulations, the identity of the products shall be maintained, and they shall not be shipped or delivered for shipment from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia, or otherwise dealt with as products prepared under the regulations. The licensee shall adopt and enforce all necessary measures and shall comply with all such directions as the Chief may prescribe for carrying out the regulations. It shall be the responsibility of the licensee, irrespective of Branch supervision, so to prepare and test each biological product, as set forth in the regulations, that it will not be worthless, contaminated, dangerous, or harmful.

IMPORT PERMITS FOR BIOLOGICAL PRODUCTS

§ 102.26 Import permits required. Each person importing biological products shall hold an unexpired, unsuspended, and unrevoked permit issued by the Secretary.

§ 102.27 Application for import permit; requirements. (a) Each person desiring to import biological products shall make application in writing to the Secretary for a permit. The application shall specify the port or ports of entry at which the imported products will be cleared through the customs. Blank forms of application will be furnished upon request addressed to the Animal Inspection and Quarantine Branch, Washington, D. C.

(b) Each application for a permit shall be accompanied by the affidavit of the actual manufacturer presented before an American consular officer, giving the name of the country, and the city, town or other location, where the biological products named therein are prepared, stating that said products are not worthless, contaminated, dangerous, or harmful, and stating whether the products were derived from animals,

and, if so derived, the name of the species, and that such animals have not been exposed to any infectious or contagious disease, except as may have been essential in the preparation of the products and as specified in the affidavit.

(c) Each application for a permit shall be accompanied by the written consent of the actual manufacturer that properly accredited employees of the Department shall have the privilege of inspecting, without previous notification, and at such times as may be demanded by the aforesaid employees, all parts of the establishment at which such biological products were prepared, all processes of preparation, and all records relative to the preparation of such products.

(d) Each application for a permit shall be accompanied by information regarding all claims to be made on labels and in advertising matter used in connection with or related to the biological products to be imported, and a description of the methods of producing and testing the products used by the manufacturer. A permit will not be issued for the importation of any biological product unless written assurance is furnished that the product will not be so advertised as to mislead or deceive the purchaser, and that the package or container in which the same is intended to be sold, bartered, exchanged, shipped, or imported will bear or contain no statement, design, or device which is false or misleading in any particular, and unless the product meets the applicable requirements of the regulations in Part 112 of this chapter.

§ 102.28 Import permits; number, form, and termination. Permits shall be numbered and shall be in the following form:

UNITED STATES VETERINARY PERMIT NO. _____

BIOLOGICAL PRODUCTS

Washington, D. C., _____

This is to certify that, pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, _____, State of _____, is hereby authorized, so far as the jurisdiction of the United States Department of Agriculture is concerned, to import _____ manufactured by _____, of _____, into the United States through the port of _____ during the calendar year of _____.

This permit is subject to suspension or revocation if the permittee violates or fails to comply with said act or the regulations made thereunder.

_____

Secretary of Agriculture

Countersigned:

_____

Chief, Animal Inspection and Quarantine Branch

Each permit shall terminate at the end of the calendar year for which it is issued.

SUSPENSION OR REVOCATION OF LICENSES AND PERMITS, AND NOTICES RE DANGEROUS PRODUCTS

§ 102.51 Suspension or revocation. (a) A license or permit issued under the Virus-Serum-Toxin Act may be formally suspended or revoked after opportunity for hearing has been accorded the licensee or permittee as provided in Part 123 of this chapter, if the Secretary is satisfied that the license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation contrary to said act of any worthless, contaminated, dangerous, or harmful biological product. Such use may be found to exist if:

(1) The construction of the establishment in which the biological product is prepared is defective, or the establishment is not conducted as required by the regulations;

(2) The methods of preparation of the product are faulty, or the product contains impurities or lacks potency;

(3) The product is so labeled or advertised as to mislead or deceive the purchaser in any particular;

(4) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations; or

(5) The license or permit is otherwise used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation, contrary to the Virus-Serum-Toxin Act, of any worthless, contaminated, dangerous, or harmful biological product.

(b) In case of willfulness or where the public health, interest, or safety so requires, however, the Secretary may without hearing informally suspend such license or permit upon the grounds set forth in paragraph (a) of this section pending determination of formal proceedings under Part 123 of

this chapter for suspension or revocation of the license or permit.

§ 102.52 Notices re dangerous biological products. If at any time it appears that the preparation, sale, barter, exchange, shipment, or importation, as provided in the Virus-Serum-Toxin Act, of any biological product by any person holding a license or permit may be dangerous in the treatment of domestic animals, the Secretary may without hearing notify the licensee or permittee, and pending determination of formal proceedings instituted under Part 123 of this chapter for suspension or revocation of the license or permit insofar as it authorizes the manufacture or importation of the particular product, no person so notified shall thereafter so prepare, sell, barter, exchange, ship, deliver for shipment, or import such product.

ASSIGNMENT OF INSPECTORS AND FACILITIES

§ 102.76 Inspections of licensed establishments. (a) Any inspector shall be permitted to enter any establishment licensed under the regulations at any hour during the day or night, and such inspector shall be permitted to inspect, without previous notification, the entire premises of the establishment, including all buildings, compartments, and other places, all biological products, and organisms and vectors in the establishment, and all equipment, such as chemicals, instruments, apparatus, and the like, and the methods used in the manufacture of, and all records maintained relative to, biological products at such establishment.

(b) Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession. This badge shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the licensed establishment and premises and to any place at any time for the purpose of making an inspection pursuant to paragraph (a) of this section.

§ 102.77 Facilities. When required by the Chief or the inspector in charge, the following facilities, and such others as may be essential to efficient conduct of inspection, shall be provided in each licensed establishment.

(a) Satisfactory pens, equipment, and assistance for conducting tests required in accordance with the regulations in this subchapter;

(b) The following special facilities in establishments producing anti-hog-cholera serum and hog-cholera virus:

(1) Separate laboratory rooms for serum and virus,

(2) A separate room in which animals shall be washed and cleaned,

(3) A separate room in which animals shall be finally prepared for bleeding or hyperimmunizing,

(4) A separate room or adequate facilities for conducting autopsies,

(5) A separate room for preparation and mixing of biological products,

(6) A separate room for washing and sterilizing equipment,

(7) Clean cloths, which shall be kept damp when in use, to be used for covering virus pigs and final bleeders during all operations incident to the collection of blood, and

(8) Dust screens for all outside doors, openings, and unsealed windows;

(c) Suitable rooms and compartments in such places, and containers, and the like, in such numbers as may be necessary for holding biological products: *Provided*, That such rooms and compartments, and containers, and the like shall be capable of being secured under locks or seals furnished by the Branch, and the keys of said locks shall not leave the custody of the inspectors;

(d) Suitable containers satisfactorily equipped for thoroughly mixing batches of all biological products; and

(e) Automatic recording thermometers or gages equipped for locking or sealing as provided in paragraph (c) of this section, and other thermometers which will register temperatures accurately and satisfactorily for use as required by the regulations.

§ 102.78 Overtime work at licensed establishments. The management of a licensed establishment desiring to work under conditions which will require the services of an employee of the Branch on Saturday, Sunday, or a holiday, or for more than eight hours of any other day, shall sufficiently in advance of the period of overtime, request the inspector in charge or his assistant to provide inspection service during such overtime period, and shall pay the Administrator of the Agricultural Research Service an amount sufficient to reimburse the service for the cost of the inspection service so furnished. It will be administratively determined from time to time which days constitute holidays.

320931—54——3

PART 108—SANITATION AT LICENSED ESTABLISHMENTS

Sec.

§ 108.1 Remodeling and additions; plans and specifications. Triplicate copies of plans properly drawn to scale, and of specifications, including plumbing and drainage, for remodeling licensed establishments and for new structures at licensed establishments shall be submitted to the Chief in advance of construction.

§ 108.2 Stables and premises. Stables or other premises for animals used in the production or testing of biological products at licensed establishments shall be properly ventilated and lighted, appropriately drained and guttered, and kept in sanitary condition.

§ 108.3 Segregation of animals. Animals infected with or exposed to any dangerous, infectious, contagious, or communicable disease shall be effectively segregated at licensed establishments.

§ 108.4 Location of licensed establishments. (a) Licensed establishments shall be so located and so constructed that disease will not spread therefrom, and suitable arrangements shall be made for the disposal of all refuse.

(b) Direct communication to licensed establishments shall not be maintained from public stockyards, abattoir pens, or other places in which animals are received or held for any purpose.

§ 108.5 Precautions. All biological products prepared at licensed establishments shall be prepared, handled, and distributed under the Virus-Serum-Toxin Act with due sanitary precautions, and all such biological products to be shipped or delivered under said act shall be securely packed.

§ 108.6 **Construction.** The floors, walls, ceilings, partitions, posts, doors, and all other parts of all structures at licensed establishments shall be of such material, construction, and finish as can be readily and thoroughly cleaned.

§ 108.7 **Dangerous organisms and products.** Rooms or compartments separate from the remainder of the establishment shall be provided at licensed establishments for preparing, handling, and storing virulent or dangerous organisms and products.

§ 108.8 **Light and ventilation.** All rooms and compartments at licensed establishments shall have abundant light and sufficient ventilation to insure sanitary and hygienic conditions.

§ 108.9 **Dressing rooms and other facilities.** (a) Each licensed establishment shall have dressing and toilet rooms and urinals sufficient in number, ample in size, conveniently located, properly ventilated, and meeting all requirements of the regulations as to sanitary construction and equipment. These rooms and facilities shall be separate from rooms and compartments in which any biological product is prepared, handled, or stored.

(b) Each licensed establishment shall have modern lavatory accommodations, including running hot and cold water, soap, towels, and the like. These shall be so located in the establishments as to make them readily accessible to all persons handling biological products.

§ 108.10 **Drainage and plumbing.** There shall be an efficient drainage and plumbing system for each licensed establishment and premises thereof, and all drains and gutters shall be properly installed with approved traps and vents.

§ 108.11 **Water supply.** The supply of hot and cold water at licensed establishments shall be ample and clean. Adequate facilities shall be provided for the distribution of water in each establishment and for the washing of all containers, machinery, instruments, other equipment, and animals used in the preparation, handling, or storing of any biological product.

§ 108.12 **Rooms and equipment.** All rooms, compartments, and other places used in connection with the preparation, handling, or storing of any biological product at licensed establishments shall be of such material, construction, and design as can be readily and thoroughly cleaned. All containers, instruments, and other equipment shall be cleaned

and sterilized and so handled thereafter as to afford protection from contamination. Containers, instruments, and other apparatus and equipment used for preparing, handling, or storing virulent or dangerous organisms or products shall not be used for handling, preparing, or storing other forms of biological products.

§ 108.13 Hands and clothing. (a) All employees of licensed establishments who handle biological products shall keep their hands and clothing clean. The hands of such employees shall not come in contact with any biological product or with any part of sterilized containers, instruments, or other equipment which may come in contact with such products.

(b) Caps, gowns, and other outer clothing worn by persons while handling any biological product shall be of clean, white material whenever practicable. All persons, immediately before entering the operating or laboratory rooms of a licensed establishment, shall change their outer clothing or effectively cover the same with gowns or other satisfactory garments.

§ 108.14 Outer premises. The outer premises of licensed establishments, embracing docks, driveways, approaches, yards, pens, chutes, and alleys, shall be drained properly and kept in a clean and orderly condition. No nuisance shall be allowed in any licensed establishment or on its premises.

§ 108.15 Flies and other vermin. Every practicable precaution shall be taken to keep licensed establishments free of flies, rats, mice, and other vermin. The accumulation, on the premises of an establishment, of any material in which flies or other vermin may breed is forbidden.

§ 108.16 Carcasses, refuse materials, and biological products. All parts of the carcasses of animals producing viruses, all other dead animals and parts and refuse, all materials unsatisfactory for production purposes, all biological products unsatisfactory for marketing, and all worthless, contaminated, dangerous, or harmful biological products, shall be incinerated or otherwise disposed of by licensees as may be required by the Chief.

§ 108.17 Smoking or expectorating, etc. Such practices as smoking in laboratories or expectorating on the floors of any room, compartment, or place in which biological products are prepared, handled, or stored at licensed establishments are prohibited.

PART 109—STERILIZATION AT LICENSED ESTABLISHMENTS

Sec.
109.1 Equipment and the like.
109.2 Sterilizers.

§ 109.1 Equipment and the like. (a) All containers, instruments, and other apparatus and equipment, before being used in preparing, handling, or storing biological products, at a licensed establishment, except as otherwise prescribed herein, shall be thoroughly sterilized by live steam at a temperature of at least 120° C. for not less than one-half hour, or by dry heat at a temperature of at least 160° C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the Chief.

(b) Instruments which are found to be damaged by exposure to the degree of heat prescribed in this section, after having been thoroughly cleaned, may be sterilized by boiling for not less than 15 minutes, provided apparatus satisfactory to the inspector in charge is furnished for this purpose.

§ 109.2 Sterilizers. Steam and dry-heat sterilizers used in connection with the production of anti-hog-cholera serum and hog-cholera virus at licensed establishments shall be equipped with automatic temperature-recording gages. Charts used on these gages shall be available at all times for examination by inspectors.

PART 112—LABELS AND SAMPLES

LABELS

Sec.
112.1 Containers.
112.2 Required and permitted information.
112.3 Reference to distributors.
112.4 Review and approval of labels and other material.

SAMPLES

112.26 Collection and handling of samples.
112.27 Selection, marking, and holding by licensee.

LABELS

§ 112.1 Containers. (a) Each immediate or true container of biological products prepared at a licensed establishment or imported by a licensee or permittee, in compliance

with the regulations and found not to be worthless, contaminated, dangerous, or harmful, shall be labeled as provided in this part.

(b) No container of any biological product which has not been so prepared and found not to be worthless, contaminated, dangerous, or harmful shall bear such a label, except that containers of anti-hog-cholera serum and hog-cholera virus prepared at licensed establishments, and such other products of such establishments as the Chief may permit, may be labeled before the products are released for marketing: *Provided*, Anti-hog-cholera serum and hog-cholera virus labeling is done under the direct supervision of an inspector and the products immediately thereafter are placed under Branch lock, where they are held until released for marketing. No person shall have access to the compartment in which such labeled products are held under such lock except in the immediate presence of an inspector.

(c) No person shall apply or affix, or cause to be applied or affixed, any label, stamp, or mark to any biological product prepared or received in a licensed establishment or imported except in compliance with the regulations. Suitable tags or labels of a distinct design shall be used for identifying all biological products while in course of preparation at licensed establishments.

§ 112.2 Required and permitted information. (a) Except as provided by the Chief, each label of a biological product prepared at a licensed establishment or imported shall include the following:

(1) The true name of the product which name shall be identical with that shown in the license or permit under which the product is prepared or imported and shall be prominently lettered and placed giving equal emphasis to each word composing it;

(2) The name and address of the licensee or permittee: *Provided*, That when the licensee has more than one establishment, one street address only shall be given, although the general location of each licensed establishment in such case may be stated;

(3) The license or permit number assigned by the Department which shall be shown only in one of the following forms, respectively: "U. S. Veterinary License No. ____," or "U. S. Vet. License No. ____," or "U. S. Veterinary Permit No. ____," or "U. S. Vet. Permit No. ____";

(4) A serial number by which the product can be identified with the manufacturer's records of preparation;

(5) A permitted expiration date affixed before the product is removed from the manufacturer's establishment;

(6) A dosage table and full instructions for the proper use of the product or a statement in the case of very small labels as to where such information is to be found;

(7) The quantity of the contents of each immediate or true container in cubic centimeters, units, grams, or milligrams;

(8) Instructions to keep the product at a temperature of not over 45° F.: *Provided*, That all labels, circulars, and the like for liquid Brucella abortus vaccine and rabies vaccine shall include a warning against freezing and instructions to keep the product under refrigeration at 35° to 45° F.;

(9) In the case of a multiple-dose container, a warning that all of the product should be used at the time the container is first opened, except as provided in subparagraph (13) of this paragraph;

(10) In the case of a product composed of viable or dangerous organisms or viruses, the notice "Burn this container and all unused contents" prominently placed and lettered and affixed to the immediate or true container of such product, except as provided in subparagraph (13) of this paragraph;

(11) In the case of subcutaneous tuberculin, a statement indicating the quantity of Koch's old tuberculin (K. O. T.) in each cubic centimeter, disk, or the like of the product, and recommendations regarding the minimum dose to be administered: *Provided*, That this dose for subcutaneous use shall be not less than the equivalent of 0.5 gram K. O. T.;

(12) In the case of a product which contains an antibiotic added during the production process, the statement "Contains _____ as a preservative", or an equivalent statement, indicating the antibiotic added;

(13) (i) In the case of a diluent which is to be removed from its container and entirely added to a desiccated biological product, the label of such diluent is exempt from the provisions of subparagraphs (9) and (10) of this paragraph;

(ii) In the case of a diluent with which a desiccated biological product is to come in contact while the diluent is in its original container, the label of such diluent must conform to the provisions of subparagraphs (9) and (10) of this paragraph;

(iii) In the case of a desiccated biological product which is to be added to a diluent and never returned to the original container, the label of such desiccated biological product shall conform to the provisions of subparagraph (10) of this paragraph but is exempt from the provisions of subparagraph (9) of this paragraph; and

(14) All other similar information required by the Chief.

(b) Labels of biological products prepared at licensed establishments or imported may also include any other statement which is not false or misleading.

(c) Labels of biological products prepared at licensed establishments or imported shall not include any statement, design, or device which overshadows the true name of the product as licensed or which is false or misleading in any particular or which may otherwise deceive the purchaser.

§ 112.3 Reference to distributors. When any biological product is to be distributed under the Virus-Serum-Toxin Act by any person other than the one holding a license to produce, or a permit to import, such product, and the name and address of the distributing person are to appear on the labels of the containers thereof a statement shall be made on the labels indicating that such person is the distributor of the biological product. The name and address of the distributor shall not appear in any form or manner indicating that he is the producer of the product or operating under the license or permit shown on the label. The terms "distributor," "distributors," "distributed by," or equivalent terms may be used if prominently and properly placed and lettered, in connection with the name and address of the distributing person: *Provided*, The same are not so used as to be either false or misleading. Reference to the distributing person shall be made by name and address only.

§ 112.4 Review and approval of labels and other material. (a) Except as otherwise provided in this section, quadruplicate copies of all labels, circulars, and enclosures distributed with biological products prepared by licensed establishments or imported shall be submitted to the Chief for review and approval before they are placed in use. For the convenience and guidance of licensees and permittees, sketches or proofs of new labels and the like may be submitted in triplicate to the Chief for review and approval, and in this case the preparation of finished labels and the like shall be deferred until copies of such sketches or proofs are returned to the licensee or permittee.

(b) Tags, stickers, and the like used to identify products or materials during process of production or testing, if not false or deceptive, may be used by licensees with the permission of the inspector in charge.

(c) The inspector in charge may permit the use by licensees of approved labels and the like which have been modified as follows:

(1) When all features of the label are proportionately enlarged and the general arrangement including colors remains the same; or

(2) When the label is translated into a foreign language without other material change.

(d) As of February 1 of each year or oftener on request by the Chief, licensees shall submit to him, through the office of the inspector in charge, lists of labels and the like which they will continue in actual use. Each shall be properly identified by date of approval, name of product, and number if used.

SAMPLES

§ 112.26 Collection and handling of samples. (a) Samples of biological products shall be collected only by authorized officers, agents, or employees of the Department.

(b) Samples may be purchased in the open market, and the marks, brands, or tags upon the package or wrapper thereof shall be noted. The collector shall note the names of the vendor and agent of the vendor who made the sale, together with the date of purchase. The collector shall select representative samples.

(c) All samples or parts of samples shall be sealed by the collector and marked for identification and future reference.

§ 112.27 Selection, marketing, testing, and holding by licensee. (a) Representative samples of each batch of every biological product, except anti-hog-cholera serum, hog-cholera vaccine, and hog-cholera virus, shall be selected at random from packages finished for marketing by designated laboratory employees in each licensed establishment. Said representative samples shall include two samples reserved for Branch call and such other samples as may be required by the licensee for examination and testing. Each sample reserved for Branch call shall (1) consist of two or more containers and the package (or packages) shall be sealed, dated, and initialed when taken; (2) be adequate in quan-

tity for appropriate examination and testing; (3) be truly representative of the batch which is to be marketed and be in true containers; and (4) be held by the licensee at least 6 months after the latest expiration date stated on the labels.

(b) A special compartment or the equivalent shall be set aside by the licensee for the exclusive holding of the two samples reserved for Branch call under refrigeration at 35° to 45° F. The samples shall be stored systematically for ready reference and procurement if and when requested by the Branch.

PART 114—MISCELLANEOUS REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Sec.

§ 114.1 Composition of products. Organisms or viruses used in the production at licensed establishments of bacterins, vaccines, toxins, and the like shall be derived from the causative agents of the diseases or conditions against which the products are to be used, and shall be free from the causative agents of other diseases or conditions.

§ 114.2 Methods. (a) All biological products shall be prepared, handled, stored, marked, treated, and tested by licensees in accordance with methods described in the licensees' outlines provided for under this section, unless other methods are prescribed or permitted by the Chief in which case such other methods shall be used.

(b) An outline, describing fully the entire process of preparing, handling, storing, marking, treating, and testing each biological product except anti-hog-cholera serum and hog-cholera virus, shall be submitted by each licensee to the Branch. Tests that are applicable and necessary to prevent the marketing of an unsatisfactory product shall be made by the licensee. Such tests include sterility, safety, and potency tests and tests for determining agglutination and comple-

ment fixation titer, and the like. Each outline shall clearly state a definite expiration date for the product and on what it is based. Each outline to which no objections are made by the Chief will be stamped, with the date filed, and copies of such outlines will be returned to the licensee. An outline may be followed only after such action has been taken. An outline so processed must be followed by the licensee unless and until amended in the same manner or the licensee is directed to discontinue following such outline because of objections made to it at any time by the Chief. When such objections are made, unless the licensee modifies his outline to meet them, the Chief may, after affording opportunity for hearing to the licensee, prescribe the method of preparing, handling, storing, marking, treating, or testing the particular product to be observed by the licensee. Pending such action by the Chief, the licensee may continue to use such outline except that where the public health, interest, or safety so requires, the Chief may upon notice to the licensee, suspend immediately approval of the outline and thereupon the licensee shall not use such outline in the production of biological products under the Virus-Serum-Toxin Act unless and until subsequent notice of withdrawal of such suspension is given to the licensee.

§ 114.3 **Serums, equine and bovine.** (a) Equine and bovine serums produced at licensed establishments shall be derived from the blood of healthy animals. No serum-producing animal shall be given antigen containing Brucella organisms or their derivatives without approval of the Chief. Detailed records relative to any tests on the animal and to the antigens used in treating serum-producing animals shall be maintained by the licensee.

(b) Serum and aggressin of equine origin produced at licensed establishments shall be heated at 58.5° C. for 60 minutes, with a tolerance of 0.5° above and below that temperature, by methods prescribed in this section, and serum of bovine origin shall be heated in like manner for 30 minutes. Serum shall contain no preservative at the time of heating.

(c) Serum heated as provided in paragraph (b) of this section, shall be cooled immediately thereafter to 15° C. or lower, and thus held until it is properly preserved. It shall be preserved, mixed, and tested by methods described in the licensee's outline.

(d) Units of equine serum heated as provided in paragraph (b) of this section, may be tested for toxicity on one

or more horses by injecting, intravenously, each of the test horses with at least 100 cc. of a representative sample thereof. Should the test horses show a reaction due to the serum injected, the product shall not be marketed unless and until the toxic fraction is removed or is shown to be harmless.

(e) Bulbs and other parts of recording thermometers at licensed establishments which are to be placed within heating containers, when not in actual use shall be submerged in a 5-percent phenol solution.

(f) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

(g) Licensees shall keep detailed records relative to each unit of serum as pasteurized and each batch of serum as prepared for marketing. Recording thermometer charts must bear full information concerning the serum heated and tests made of the equipment.

(h) Metal serum containers, each having a capacity of approximately 50 liters, shall be used in licensed establishments. During the heating process these containers shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is submerged at least 2 inches beneath the surface of the water. Filling must be done at a point which is below the surface of the water at the time of heating. Each serum container shall be equipped with a motor-driven agitator and a separate automatic recording thermometer, and shall have a lid attached to the container so as to withstand approximately 15 pounds' pressure without leakage, when submerged in water.

(i) The water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62° C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separate from the serum-container jacket.

(j) All pasteurizing equipment must be acceptable to the Branch and meet all necessary tests.

§ 114.4 Brucella cultures. Only those cultures of Brucella abortus organisms known to be acceptable to the Branch shall be used in preparing Brucella abortus vaccine in licensed establishments. Cultures for this purpose will be supplied by the Branch upon request. Cultures of Brucella suis

must not be admitted to or handled in licensed establishments without approval of the Chief.

§ 114.5 **Brucella abortus vaccine; marketing and use.** (a) Licensees' production outlines for Brucella abortus vaccine shall specify, among other things, the minimum number of viable Brucella abortus organisms per cubic centimeter that shall be present in the product until the end of the period of use indicated by the expiration date. The expiration date for the liquid form of this vaccine shall not exceed 3 months from the date of production (harvesting), and for the desiccated form shall not exceed 15 months from the date of production (harvesting). The vaccine shall be marketed only in vials of resistant glass of low alkalinity and uniform stability, and all other glass containers used in preparation of the product shall be of like resistance.

(b) Freshly prepared Brucella abortus vaccine shall contain, when subjected to testing, not less than 10 billion viable Brucella abortus organisms per cubic centimeter. The vaccine also shall contain not less than 5 billion viable Brucella abortus organisms per cubic centimeter until the end of the period of use as indicated by the expiration date recorded on all labels used on or in connection with each immediate or true container of the same mixture or batch.

§ 114.6 **Fowl-pox vaccine, laryngotracheitis vaccine, and Newcastle disease vaccine.** Licensed establishments shall test each batch of fowl-pox vaccine, including pigeon-pox, laryngotracheitis vaccine, and Newcastle disease vaccine as provided in this section to determine whether it is free from the causative agents of extraneous diseases.

(a) **Fowl-pox vaccine.** For testing each batch of fowl-pox vaccine, 12 healthy cockerels or other suitable young chickens of the same source shall be made available at the same time. This group shall have been immunized for at least 21 days with fowl-pox vaccine, previously tested and found satisfactory.

(1) Three of the test birds selected shall be injected subcutaneously with 10 times the field dose of the vaccine to be tested. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from other viruses and etiological agents of septicemic diseases.

(2) Three of the test birds selected shall be injected intratracheally with 10 times the field dose of the vaccine to be tested. The vaccine as tested shall be prepared exactly as

the product is to be used in the field. This group should serve to indicate whether the product is free from the etiological agents of laryngotracheitis and similar diseases.

(3) Three of the test birds selected shall be injected intranasally with 0.2 cc. of the vaccine prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from the etiological agents of coryza and similar diseases.

(4) The three remaining birds selected shall be isolated and held as controls under observation for at least 21 days.

(5) All the treated birds shall be observed daily for at least 21 days. All the test birds that succumb shall be subjected to a careful post mortem examination by a competent veterinarian. The product shall be withheld from the market until it and the test birds are shown to be free of the causative agents of any extraneous disease. No bird shall be used more than once in making tests, and only healthy birds shall be removed from the premises.

(b) **Laryngotracheitis vaccine.** For testing each batch of laryngotracheitis vaccine, 12 healthy cockerels or other suitable young chickens of the same source shall be made available at the same time. This group shall have been immunized for at least 14 days with laryngotracheitis vaccine previously tested and found satisfactory.

(1) Three of the test birds selected shall be injected subcutaneously with 10 times the field dose of the vaccine to be tested. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from other viruses and etiological agents of septicemic diseases.

(2) Three of the test birds selected shall be treated by applying at least 10 times the field dose of the vaccine to be tested to a scarified area of at least 1 square centimeter on the comb of each bird. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from the virus of fowl-pox.

(3) Three of the test birds selected shall be injected intranasally with 0.2 cc. of the vaccine to be tested. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from the etiological agents of coryza and similar diseases.

(4) The three remaining birds selected shall be isolated and held as controls under observation for at least 21 days.

(5) All the treated birds shall be observed daily for at least 21 days. All the test birds that succumb shall be subjected to a post mortem examination by a competent veterinarian. The product shall be withheld from the market until it and the test birds are shown to be free of the causative agents of any extraneous disease. No bird shall be used more than once in making tests, and only healthy birds shall be removed from the premises.

(c) **Newcastle disease vaccine.** For testing each batch of Newcastle disease vaccine, 15 healthy cockerels or other suitable young chickens of the same source shall be made available at the same time. This group shall have been immunized for at least 14 days with Newcastle disease vaccine previously tested and found satisfactory.

(1) Three of the test birds selected shall be injected subcutaneously with 10 times the field dose of the vaccine to be tested. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from other viruses and etiological agents of septicemic diseases.

(2) Three of the test birds selected shall be injected intratracheally with 10 times the field dose of the vaccine to be tested. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from viruses of laryngotracheitis and similar diseases.

(3) Three of the test birds selected shall be injected intranasally with 0.2 cc. of the vaccine prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from viruses of coryza and similar diseases.

(4) Three of the test birds selected shall be treated by applying at least 10 times the field dose of the vaccine to be tested to a scarified area of at least 1 square centimeter on the comb of each bird. The vaccine as tested shall be prepared exactly as the product is to be used in the field. This group should serve to indicate whether the product is free from the virus of fowl-pox.

(5) The three remaining birds selected shall be isolated and held as controls under observation for at least 21 days.

(6) All the treated birds shall be observed daily for at least 21 days. All the test birds that succumb shall be sub-

jected to a post mortem examination by a competent veterinarian. The product shall be withheld from the market until it and the test birds are shown to be free of the causative agents of any extraneous disease. No bird shall be used more than once in making tests, and only healthy birds shall be removed from the premises.

§ 114.7 **Rabies vaccine.** Licensees producing killed rabies vaccine shall adhere to the following requirements pertaining to the preparation and testing of this product for safety and potency:

(a) The fixed virus of rabies material shall be treated with phenol or by other means permitted by the Chief to render it safe without materially reducing the antigenicity of the vaccine.

(b) Rabies vaccine shall be collected in batches and mixed thoroughly in a single container. The product in the completed batch shall consist not less than 20 percent of fixed virus material unless otherwise authorized by the Chief.

(c) Safety tests shall be made by injecting subdurally laboratory animals with a representative sample of rabies vaccine. Each batch not in excess of 100,000 cc. completed for marketing shall be tested by thus injecting each of not less than two rabbits with not less than 0.2 cc. and each of not less than five mice with 0.03 cc. for each 20,000 cc. or fraction thereof. The test animals shall be held under observation for at least 14 days.

(d) Each batch of completed vaccine not in excess of 100,000 cc. shall be tested by the licensee for protective value. Each batch to be marketed shall show a protective titer of at least 1,000 m. l. d. when tested on suitable mice against the permitted standard challenge virus.

(e) Rabies vaccine, prepared for marketing, which contains the living virus of rabies or which is worthless, contaminated, dangerous, or harmful, shall not be marketed and shall be destroyed under the provisions of § 108.16 of this chapter.

§ 114.8 **Tetanus antitoxin.** (a) All containers of tetanus antitoxin prepared by licensees for marketing in the United States shall contain not less than 1,500 units and be labeled to recommend not less than this quantity as a minimum prophylactic dose.

(b) When tetanus antitoxin is prepared by licensees for export, 500 units may be recommended on the label as a mini-

mum prophylactic dose provided the labeling clearly indicates that the product is for export. There shall be printed conspicuously on each label the word "export," with the name and address of the distributor located in the foreign country.

(c) The immunity unit for measuring the strength of tetanus antitoxin shall be 10 times the least quantity of antitetanic serum necessary to save the life of a 350-gm. guinea pig for 96 hours against the dose of standard toxin permitted under the regulations.

§ 114.9 Mixing biological products. Each batch of biological product, when in liquid form, shall be mixed thoroughly in a single container and be constantly agitated during bottling operations at licensed establishments. Serial numbers in sequence, with any other markings that may be necessary for ready identification of the batch, shall be applied to identify it with the records of preparation and labeling.

§ 114.10 Phenol determination. As an aid in meeting requirements for the preservation of anti-hog-cholera serum and hog-cholera virus with phenol, employees of the Branch trained in making the field phenol test will instruct licensed-establishment employees fully in the technique of making this test. A general description and directions for making the field phenol test known as the "P–2 Test" are available on application to the Branch. The necessary reagents for such use will be supplied by the Branch through inspectors in charge on request. Licensees shall use the field phenol test on all batches of preserving solutions and hog-cholera virus. Branch inspectors will make such check tests as may be warranted.

§ 114.11 Temperature and light. Biological products at licensed establishments shall be protected at all times against light and detrimental temperatures. Furthermore, such products, after completion, shall be kept under refrigeration at 35° to 45° F.

§ 114.12 Branch tests. Whenever deemed necessary, a licensee may be required by the inspector in charge to withhold biological products from the market until representative samples have been tested by the Branch and the batches concerned released by the Branch for marketing. These samples shall be taken as authorized by the Branch.

320931—54——5

PART 115—REINSPECTION

§ 115.1 Reinspection. All biological products, the containers of which bear United States veterinary license numbers or United States veterinary permit numbers or other marks required by these regulations, may be inspected at any time or place. If, as a result of such inspection, it appears that any such product, even though prepared in a licensed establishment or imported under permit issued by the Secretary, is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice thereof to the manufacturer or importer and to any jobbers, wholesalers, dealers, or other persons known to have any of such product in their possession. Unless and until the Secretary shall otherwise direct, no person so notified shall thereafter sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product from any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia. However, failure to receive such notice shall not excuse any person from compliance with the Virus-Serum-Toxin Act.

PART 116—RECORDS AND REPORTS

RECORDS

REPORTS

RECORDS

§ 116.1 Maintenance of records. Permanent, detailed records of the results of tests for purity and potency and of the methods of preservation of each batch of biological products shall be kept by each licensee. Biological products prepared in foreign countries shall be eligible for importation into the United States only if the foreign manufacturer of such products also maintains such records. Permanent, detailed records in form satisfactory to the Chief shall be maintained by each licensee, each distributor, and each importer, showing the sale, shipment, or other disposition made of the biological products handled by such person.

§ 116.2 **Special record requirements.** Licensees preparing anti-hog-cholera serum and hog-cholera virus shall observe the following requirements:

(a) **Work sheets—(1) Virus pigs.** Work sheets for virus pigs shall show the tag number, date of admission to the premises, date of inoculation, and serial number and dose of virus used. Such work sheets shall show the temperature and physical condition of each pig when this is required by the regulations. They shall also show whether the virus collected from each pig was used in hyperimmunizing virus, simultaneous virus, or inoculating virus, or was destroyed. In the case of pigs intended for the production of simultaneous virus, the work sheet shall be prepared by the licensee in triplicate and the second carbon copy shall be furnished the inspector on the date of inoculation, except when the group is not designated as containing simultaneous virus pigs until the third day after the date of inoculation. In the latter case the work sheet shall be prepared in triplicate on the third day after inoculation to show the tag number and other information required by the regulations for each pig in the group and the second carbon copy shall then be furnished to the inspector. In any case, when the original and first carbon copies are completed, the first carbon copy shall be delivered to the inspector. All groups of pigs from which simultaneous virus will be selected shall be held in pens separate from other pigs.

(2) **Hyperimmunization of immune hogs.** Work sheets for hyperimmunization of immune hogs shall show the temperature and the tag number of each animal, actual weight at time of hyperimmunization, and the serial number and dose of virus injected. The net quantity injected into each group of animals and the number of the group to which each animal belongs also shall be recorded. This work sheet shall be prepared in duplicate, and the carbon copy shall be furnished to the inspector.

(3) **Bleeding of hyperimmune hogs.** Work sheets for bleeding of hyperimmunized hogs shall show the group number of the hogs, the temperature and tag number of each animal, and the class of bleeding. The work sheet shall be prepared in duplicate and furnished to the inspector in advance of actual bleeding of the animals shown thereon. Upon receipt of the work sheet, the inspector shall check it with his records, and if he finds that the animals shown thereon are eligible for bleeding he shall supervise the taking and record-

ing of their temperatures. The temperature of each animal shall be recorded on the work sheet by an employee of the licensed establishment. The inspector shall indicate on the work sheet those animals that are rejected, return the original copy to the licensee, and retain the duplicate.

(4) **Serum preparation.** Work sheets for the clarification of anti-hog-cholera serum shall show the number of the group to which the hogs belong, and the class and total number of bleedings involved, with the information required in this subparagraph relating to each working unit, as defined in § 119.23 (a) (3) of this chapter. The information relating to the working unit shall include the total quantity of whole or defibrinated blood used and the total quantity of clarifying solutions. The quantity of each clarifying solution shall be recorded separately. The quantity of serum recovered (gross), the total quantity of preserving solution used, and the total quantity of preserved serum shall be recorded separately for each group. The quantity of preserved serum contained in each storage container and the number of the container shall be shown on the work sheet. This work sheet shall be prepared in quadruplicate and three carbon copies shall be furnished to the inspector.

(5) **Work sheets, specimens.** A sample form of the work sheets used in licensed establishments in connection with virus pigs, the hyperimmunization of immune hogs, the bleeding of hyperimmune hogs, and the preparation of anti-hog-cholera serum shall be filed with the Branch. A statement shall accompany each form showing in detail the manner in which it will be prepared and used.

(b) **Permanent records.** (1) Licensees shall maintain all permanent production records in ink or the equivalent. These records shall include a record of all pigs used to produce hog-cholera virus. The information on this record shall be substantially the same as that shown on the work sheets as provided in paragraph (a) of this section, and in addition it shall include the date on which each pig was killed and the serial number of the batch of virus produced. Such records shall contain information as to the total quantity in each batch of hyperimmunizing, simultaneous, or inoculating virus produced. All such records shall clearly show the particular animal or group of animals from which each batch of the product is derived. The quantity collected and the total quantity after phenolization shall be separately recorded.

(2) Records showing the hyperimmunization of immune hogs and the bleeding of hyperimmune hogs shall be maintained in permanent form.

(3) Charts of the automatic temperature-recording thermometers used in connection with the heating and cooling of anti-hog-cholera serum shall be filed as a part of the Branch station records.

(4) Complete records of the preparation and mixing of all virus and serum into batches and the bottling, testing, and labeling thereof shall be maintained as permanent records.

(5) Work sheets prepared like those used by inspectors will be deemed to meet the requirements of this part. Work sheets shall be filed by licensed establishments for reference, and if they are made in ink or the equivalent and otherwise are satisfactory they will be accepted as the permanent records.

§ 116.3 Completion of records. Records required by this part must be completed by the licensee before any portion of a batch of any product may be marketed.

REPORTS

§ 116.10 Inspection. Reports of the work of inspection carried on in licensed establishments shall be prepared and forwarded to the Branch by the inspector in charge in such form and manner as may be required by the Chief.

§ 116.11 Licensees to furnish information. Each licensee shall furnish inspectors with accurate information needed by them for making their reports pursuant to § 116.10 and shall also submit such reports as may be required by the Chief.

§ 116.12 Charts. Each licensee shall furnish the Branch, through the inspector in charge, copies of charts of all tests made of each batch of anti-hemmorrhagic-septicemia serum, anti-swine-erysipelas serum, anti-encephalomyelitis serum, encephalomyelitis vaccine, and rabies vaccine and charts for such other products as may be required by the Chief before any of the batch is marketed.

PART 117—ANIMALS

Sec.

§ 117.1 Opportunity to range in contact. All cattle, hogs, sheep, and goats, except animals admitted by certificate as provided in § 117.6, offered for admission to the premises of licensed establishments shall be afforded opportunity to range in contact with other animals as prescribed in the regulations.

§ 117.2 Contact pens. Licensees shall provide suitable pens to be known as contact pens through which all hogs, cattle, sheep, and goats shall pass before they shall be admitted to other parts of the premises of a licensed establishment, except that animals admitted under certificate as provided in § 117.6 need not pass through such pens.

§ 117.3 Contact calves. (a) Licensees shall provide healthy calves in thrifty condition, ranging from 3 to 12 months of age, and weighing less than 650 pounds for use as contact animals in contact pens. They shall be referred to as contact calves.

(b) Each contact calf shall have its left ear pierced with a hole not less than three-fourths inch in diameter and shall have a serially numbered metal tag attached to its right ear.

§ 117.4 Time held in contact. (a) Except as otherwise provided in § 117.6, each group of 200 or less sheep or goats and each group of 20 or less cattle at licensed establishments shall be held in the contact pens for at least 2 days in contact with not less than 2 contact calves, and each animal shall be allowed free range and contact with said contact calves and the other animals in the group.

(b) Except as otherwise provided in § 117.6, each group of hogs which arrives at a licensed establishment in the same conveyance shall be held in the contact pens for at least 1 day in contact with not less than 2 contact calves, except that

in the case of pigs used in testing the potency and purity of anti-hog-cholera serum, 6 hours will be sufficient. More than 1 group of such animals may be placed in the same contact pen providing the total number of hogs in the pen does not exceed 200. Each animal shall be allowed free range and contact with said contact calves and the other animals in the group. Hogs immune to hog cholera may be removed from the contract pens for hyperimmunization at any time while being held as aforesaid: *Provided*, They are returned to said pens immediately after this operation.

§ 117.5 Contact calves; holding and removal. (a) All surviving contact calves shall be held in the contact pens of licensed establishments for at least 1 month from date of admission to contact pens as contact calves.

(b) Removal of contact calves from contact pens shall be so arranged that one animal of each group of 2 will be replaced at the expiration of 1 month and the other at the expiration of 2 months.

(c) Removal of contact calves from contact pens shall be so accomplished that the animals furnished for the purpose may be used for the maximum time permitted by the preceding paragraphs of this section. A contact calf shall not be used as such more than once, but may be used for testing simultaneous virus after release as a contact animal. Contact calves shall be segregated from incoming animals for 14 days immediately before removal from the premises.

(d) Contact calves shall be subjected to thorough veterinary inspection as frequently as may be practicable in order to detect evidence of vesicular disease or other diseases. Whenever any animals on the premises show evidence of being affected with vesicular disease, rinderpest, or any other highly communicable disease, immediate and proper steps shall be taken by the licensee and the inspector in charge to prevent further dissemination of disease and to notify the Chief of the situation. In these circumstances the pen group or section group of animals shall be regarded as a unit for disposal and no attempt made to separate such group in any way unless and until a positive diagnosis is made and a definite plan of disposal agreed upon. Whenever presence of any of these conditions is suspected, removal of animal products shall be suspended and full report made to the Branch by telephone, telegram, or air mail.

§ 117.6 Certificates. (a) Animals admitted to the premises of any licensed establishment which produces anti-hog-

cholera serum and hog-cholera virus and which procures no animals from public stockyards, abattoir pens, or similar places need not be held in contact with contact calves as provided in § 117.2 if (1) the animals are for use in the production of anti-hog-cholera serum or hog-cholera virus, and (2) the licensee furnishes to the inspector in charge at the licensed establishment a certificate as provided for in paragraph (c) of this section.

(b) Pigs for special tests authorized by the Chief admitted to the premises of any licensed establishment need not be held in contact with contact calves as provided in § 117.2 if the pigs are handled as prescribed by the Chief and if the licensee furnishes to the inspector in charge at the licensed establishment a certificate as provided for in paragraph (c) of this section.

(c) Each certificate provided for in paragraphs (a) and (b) shall be signed by an authorized representative of the licensed establishment, and shall be in the following form:

_____, 19____

This is to certify that _____
(Specify number and kind of animals)
which are offered for admission to the licensed establishment of the _____ Co. are from the farm or premises of _____, in the State of _____, County of _____, Township of _____, and to the best of our knowledge and belief were on said farm or premises at least 21 days prior to this date, and were not exposed to any infectious, contagious, or communicable disease, and no new stock was brought onto said farm or premises during that time. The said animals have not been in or transported through any public stockyards, abattoir pens, or similar places, nor have they been exposed to any infectious, contagious, or communicable disease since their removal from said farm or premises.

(Signed) _____ Co.,
Per _____

§ 117.7 Examination and identification. (a) All animals presented for admission to the premises of establishments licensed to prepare anti-hog-cholera serum or hog-cholera virus shall be subjected to veterinary inspection as soon as practicable after they are received in order to determine their physical condition. No such animal shall be removed from contact pens at such establishments without veterinary inspection and permission of the supervising inspector.

(b) After examination as provided in paragraph (a) of this section, if the animals are permitted to remain upon the premises of the licensed establishment and to enter the hold-

ing pens of the establishment, they shall be given serially numbered metal tags, either prior to or at the time of inoculation or hyperimmunization.

(c) All tags used for the identification of animals shall be attached to the ears of the animals in a manner satisfactory to the inspector in charge. The tags so attached shall be the means of assisting in identifying the animals as long as they remain on the premises.

(d) All tags which are used to identify animals shall be furnished and attached by the licensee, and when said tags are not in use they shall be held under Branch lock: *Provided*, That, when required by the Chief, tags furnished by the Branch shall be used.

(e) The left ear of each animal used in testing the purity and potency of biological products shall, if of sufficient size, be pierced, when the test is begun, with a hole of not less than three-fourths inch in diameter, except that when pigs or calves are used in testing hog-cholera virus for purity as prescribed in the regulations, their right ears shall be pierced as aforesaid. Animals bearing marks of the above-prescribed character shall not be presented for use in testing the purity and potency of biological products, except that contact calves and serum-treated pigs in anti-hog-cholera serum tests, after release as prescribed in the regulations, may be used, once for testing hog-cholera virus for purity, provided they are healthy and their right ears then are pierced as aforesaid. Furthermore, animals with either ear removed or so mutilated as to prevent the detection of these identifying marks shall not be used in any test, if the missing or mutilated ears are needed to determine the suitability of the animals for test purposes as described herein.

§ 117.8 Treatment. (a) Animals used in the production or testing of biological products at licensed establishments shall not be treated with biological products other than those which are incidental to the preparation and testing of the products prepared from or tested on said animals, except with the approval of and in such manner as may be prescribed by the Chief.

(b) Contact calves shall not be immunized against diseases to which they are susceptible, with the exception of hemorrhagic septicemia. Such calves, if permitted by the inspectors in charge, may be treated with hemorrhagic-septicemia bacterin and anti-hemorrhagic-septicemia serum.

320931—54——6

§ 117.9 Hyperimmune hogs; time range with contact calves. (a) If in any specific case hyperimmune hogs are the only production animals held upon the premises of a licensed establishment, they shall be caused to range in contact with calves in the manner prescribed in § 117.2 for a period of at least 10 days prior to their being subjected to carotid or final bleeding. All animals with which hyperimmune hogs have been held in contact as provided in this section shall be held on the premises of the licensed establishment and under the observation of inspectors for at least 14 days after the hyperimmune hogs have been killed.

(b) If at any time hyperimmune hogs are subjected to tail bleeding only, those surviving shall be held under the supervision of inspectors for at least 14 days after the last tail bleeding, but subsequently shall be killed and subjected to post mortem examination as provided by the regulations.

§ 117.10 Removal of animals. Hogs, cattle, sheep, or goats shall not be removed from the premises of establishments licensed to produce anti-hog-cholera serum or hog-cholera virus without the written permission of the inspector in charge. Removal of animals from the premises of licensed establishments will be permitted by the inspector in charge under the following conditions, provided it is accomplished in such a manner as will preclude the dissemination of disease:

(a) Animals that are not in a healthy condition as determined by veterinary inspection, except when affected with a communicable disease, may be removed from licensed establishments for immediate slaughter in an abattoir operated under Federal inspection pursuant to the Meat Inspection Act (21 U. S. C. and Sup. 71 et seq.) if they are transported thereto by truck, wagon, or similar means, and not by rail: *Provided*, They are properly marked for identification and the inspector in charge of meat inspection is given due notice in advance. If such an abattoir is not accessible, the slaughter of said animals may be conducted in any convenient nonfederally inspected establishment provided the licensee signifies willingness in writing to dispose of the carcasses in compliance with the Meat Inspection Act and under the provisions of the meat inspection regulations (9 CFR, Chapter I, Subchapter A, as amended), and veterinary inspection as directed by the inspector in charge.

(b) Hogs that are in a healthy condition as determined by veterinary inspection may be removed from licensed estab-

lishments provided they are or have been treated or vaccinated and disinfected as prescribed in the regulations. Such hogs need not be treated or vaccinated or disinfected when removed for immediate slaughter at an abattoir operated under Federal inspection pursuant to the Meat Inspection Act (21 U. S. C. and Sup. 71 et seq.) or when removed to a public stockyard from which no hogs are permitted to be removed, without treatment or vaccination and disinfection under supervision of a Federal inspector, for purposes other than immediate slaughter. When hogs are removed to abattoirs or public stockyards without treatment or vaccination and disinfection as aforesaid, the licensee shall furnish the Branch with a certificate from the consignee of the animals at the abattoir or public stockyards showing their slaughter therein or receipt thereby, respectively. If the animals are not disinfected, they shall not be transported by rail or driven over public highways which are not traversed by animals from stockyards or similar places.

(c) Calves that are in a healthy condition as determined by veterinary inspection may be removed from licensed establishments after disinfection as described in § 117.12 (a). When removed to an abattoir without passing through stockyards or over public highways which are not traversed by animals from public stockyards or similar places, the animals need not be so disinfected, provided the licensee furnishes the inspector in charge a statement from the consignee of the animals certifying that the animals will be slaughtered in an abattoir named in the certificate.

(d) Pigs which survive inoculation and exposure to hog-cholera virus for the production of hog-cholera virus, and surviving control pigs in tests of anti-hog-cholera serum, may be removed from licensed establishments not earlier than 14 days subsequent to the time of inoculation and exposure as aforesaid, provided they are healthy, as determined by veterinary inspection, are treated as described in § 117.11 and are disinfected as set forth in § 117.12, except that when removed for immediate slaughter or to public stockyards or to feed lots approved by the Chief, said animals need not be so treated or disinfected. Other surviving pigs in tests of anti-hog-cholera serum and hog-cholera virus may be removed at the conclusion of the test period, subject to the conditions prescribed in this paragraph.

(e) Hyperimmune hogs or those similarly treated may be removed from licensed establishments not earlier than 14 days

subsequent to the time of hyperimmunization or inoculation: *Provided*, They are healthy, as determined by veterinary inspection, and are disinfected as prescribed in § 117.12, except that when removed for immediate slaughter or to public stockyards they may be removed on or after the 11th calendar day and need not be so disinfected.

§ 117.11 Hogs; treatment prior to removal. All hogs which require treatment or vaccination as provided in § 117.10 shall be treated with either serum alone or by the simultaneous-inoculation method, as follows:

(a) When serum alone is used, it shall have been prepared and released for marketing at an establishment holding a license from the Secretary and the dose employed shall conform to that required by the regulations.

(b) When the simultaneous-inoculation method is used, the serum and virus used shall have been prepared at an establishment holding a license from the Secretary and the doses shall be not less than those required by the regulations. After receiving this treatment they shall be held under the supervision of an inspector for a period of at least 14 days.

§ 117.12 Disinfection before removal. All animals which require disinfection as provided in § 117.10 shall be treated as follows:

(a) The feet, legs, and soiled portions of the body of calves to be removed from the licensed establishments shall be cleaned and disinfected with a 2 percent aqueous solution of cresol compound, U. S. P., or substitute therefor approved by the Chief and the animals shall then be held in noninfectious pens on the premises of the establishment until they are dry before being loaded for transportation.

(b) Hogs shall be disinfected in a 2 percent aqueous solution of cresol compound, U. S. P., or substitute therefor approved by the Chief, and shall be held in noninfectious pens on the premises for at least 3 hours before being loaded for transportation, and after disinfection they shall not be exposed to infectious pens, chutes, and the like. Hogs transported in trucks, wagons, or by similar means may be removed as soon after disinfection as they are observed by the inspector to be dry.

§ 117.13 Other requirements. All animals used in licensed establishments in the preparation or testing of veterinary biological products shall meet such requirements consistent with the regulations in this subchapter as may be prescribed by the Chief to prevent the preparation and

sale of any worthless, contaminated, dangerous, or harmful biological products.

PART 118—HOG-CHOLERA VIRUS

GENERAL REQUIREMENTS

HYPERIMMUNIZING VIRUS

SIMULTANEOUS VIRUS

GENERAL REQUIREMENTS

§ 118.1 Supervision. No operations incident to the production of hog-cholera virus in a licensed establishment shall be conducted without the knowledge or supervision of an inspector. The licensee shall notify the inspector in charge or his assistant a reasonable time in advance whenever any operations, including overtime work, are to be conducted in the licensed establishment.

§ 118.2 **Temperatures and inspection.** Pigs which are used in the production of hog-cholera virus at a licensed establishment shall be healthy, and the temperature of each animal shall be accurately taken and permanently recorded by the licensee immediately before inoculation when in the opinion of the inspector in charge this is necessary to determine the health of the animals. Each animal shall be subjected to thorough veterinary inspection immediately prior to inoculation. Temperatures of all pigs shall be accurately taken and recorded by the licensee each day subsequent to the fourth day after inoculation and at such other times as the inspector in charge may require. The temperatures of pigs that are slow or visibly sick on any working day shall be taken and recorded in like manner.

§ 118.3 **Inoculation virus.** Pigs for the production of inoculation virus at a licensed establishment shall weigh not less than 40 pounds nor more than 125 pounds each and shall be inoculated only with highly virulent hog-cholera virus. No hog-cholera virus shall be used for inoculating pigs for the production of inoculating virus, hyperimmunizing virus, or simultaneous virus for inoculating pigs in serum tests, unless it has been produced not more than 60 days prior to use and since its completion has been held only in containers of the borosilicate or equal type. These containers shall be of high resistance and low alkalinity, shall be properly marked for identification, shall be guaranteed by the manufacturer to be acceptable to the Branch, and shall meet the tests developed by the Branch for determining these qualities. Other virus may be made suitable for inoculation purposes only by passing it through pigs as prescribed in § 121.3 of this chapter. Virus derived from these pigs may be used for hyperimmunization if the animals react as prescribed in § 118.4.

§ 118.4 **Bleeding.** Pigs from which blood is to be collected for the production of hog-cholera virus at a licensed establishment shall be bled only after they have had veterinary inspection and have manifested well-marked and increasingly grave symptoms of hog cholera only, attended with progressively abnormal temperatures common to the acute type of this disease, and have been released by the inspector.

§ 118.5 **Post mortem examinations.** All pigs from which simultaneous virus is derived at licensed establishments shall be subjected to post mortem veterinary inspection. Post mortem examination of hyperimmunizing virus

pigs shall be made by trained and competent employees of the licensee. However, in all cases the examinations will be conducted under veterinary inspection, and the inspector shall observe the examination of as many pigs as possible.

§ 118.6 Recording of symptoms. A properly applied and recorded "slow" mark on a day preceding a Sunday or holiday may be regarded as equivalent to visible sickness provided the temperature of each slow pig is taken and recorded and provided the temperature is markedly abnormal. In other circumstances the slow mark should not be regarded as equivalent to visible sickness, but should be regarded as a mark applicable to that transitional stage between normal behavior and distinct visible sickness.

§ 118.7 Autopsies. Autopsies shall be conducted at licensed establishments on a sufficient number of virus pigs that succumb to obtain all possible information as to the cause of death. Licensed-establishment employees shall perform the labor incident to these examinations under the supervision of an inspector.

§ 118.8 Early visible sickness; disposition. Pigs that become visibly sick within 3 days after they have been examined for admission to the premises of a licensed establishment as prescribed by § 117.7 of this chapter, or within 4 days when the third day falls on a Sunday or holiday, must be rejected and either shall be destroyed or handled as prescribed by § 117.10 of this chapter.

§ 118.9 Defibrination and chilling. All virus shall be defibrinated promptly after collection at a licensed establishment and immediately thereafter chilled and maintained at a temperaure of not to exceed 45° F.

§ 118.10 Disposition of virus when condition unsatisfactory. (a) Virus derived from pigs which on post mortem examination do not show lesions sufficient for the inspector to make a positive diagnosis of hog cholera, when considered with the ante mortem behavior of the animal, or from pigs which are found to be affected with any other infectious, contagious, or communicable disease or in such condition as to render the virus contaminated, shall be destroyed as provided in § 108.16 of this chapter under the supervision of an inspector. Virus passed by the inspectors may be destroyed as aforesaid at the discretion of the licensee.

(b) Virus derived from pigs which are found to be affected with tuberculosis shall not be marketed but shall be destroyed, as provided in § 108.16 of this chapter, under the

supervision of an inspector, unless the lesions are slight or localized and are calcified or encapsulated.

(c) Samples of blood from pigs which on post mortem examination show evidence of concurrent affection with other disease, except highly communicable diseases referred to in § 117.5 of this chapter, together with well-defined lesions of hog cholera, may be released by the inspector to the licensee for bacteriological examination. Blood free from highly communicable diseases as aforesaid which is deemed satisfactory by the licensee after bacteriological examination may be used for hyperimmunizing purposes.

§ 118.11 Removal of hog-cholera virus. Hog-cholera virus shall not be removed from the premises of a licensed establishment unless the virus has been prepared and handled in accordance with the provisions of the regulations.

§ 118.12 Filling and labeling containers. No immediate or true container of hog-cholera virus shall be filled in whole or in part, and no label shall be affixed to such container, except under the supervision of an inspector.

HYPERIMMUNIZING VIRUS

§ 118.25 Inoculations for hyperimmunizing virus. For use in the production of hyperimmunizing virus, licensees shall inoculate healthy young pigs weighing not more than 160 pounds each with at least 2 cc. of highly virulent hog-cholera virus: *Provided*, That when hog cholera from pen infection is manifested by the animals after the fourth day subsequent to admission to the premises of the licensed establishment, they need not be so inoculated.

§ 118.26 Requirements for hyperimmunizing virus. Hyperimmunizing virus shall be collected at licensed establishments only from pigs which are observed on veterinary inspection to be visibly sick with hog cholera and which manifest well-marked and increasingly grave symptoms thereof attended with progressively abnormal temperatures common to the acute type of this disease.

SIMULTANEOUS VIRUS

§ 118.30 Inoculations of simultaneous virus. (a) For use in the production of simultaneous virus, licensees shall inoculate young healthy pigs of good quality with at least 2 cc. each of highly virulent virus. Such pigs when inocu-

lated shall weigh not less than 40 pounds nor more than 125 pounds.

(b) Pigs which are eligible only for the production of hyperimmunizing virus shall be inoculated and held in separate pens from those to be used for simultaneous virus. Such separation shall be made on or before the third day after inoculation and such pigs held thereafter in separate pens until released by the inspector.

§ 118.31 Sickness and records thereof. Simultaneous virus shall not be collected at licensed establishments from pigs which become visibly sick on or before the third day, or subsequent to the seventh day after the time of inoculation. The physical condition of all pigs from which simultaneous virus is to be collected shall be recorded daily on and after the third day subsequent to inoculation. The observations required by the regulations in this part to be made on the third day may be made on the fourth day if the third day falls on Sunday or a holiday.

§ 118.32 Requirements for simultaneous virus, etc. (a) Simultaneous virus and other hog-cholera virus intended for the inoculation of pigs for any purpose shall be collected at licensed establishments only from pigs which are observed by an inspector to be visibly sick with hog cholera within 7 days after the time of inoculation and which manifest well-marked and increasingly grave symptoms of hog cholera attended with progressively abnormal temperatures common to the acute type of this disease.

(b) Simultaneous virus shall be prepared in licensed establishments in batches of not to exceed 50,000 cc. The defibrinated blood in each batch shall not exceed 45,000 cc. and shall be mixed thoroughly in a single container before phenolization. All simultaneous virus shall be constantly agitated during the bottling operation.

§ 118.33 Samples of simultaneous virus. The following representative samples of simultaneous virus shall be taken at licensed establishments and properly identified by an inspector: (a) At time of mixing but before phenolization, (1) "purity test sample" of not less than 30 cc. in a single container, (2) "test sample A" of not less than 5 cc. in a single container; (b) After mixing and phenolization, (1) "phenol test sample" of not less than 30 cc. in one container, (2) one reserve sample of 30 cc. to be forwarded to the Branch in event the pigeon or mouse test is unsatisfactory and to be

returned to the licensee if tests of the sample are satisfactory, (3) "test sample B" of not less than 5 cc. in a single container; (c) At time of bottling, a "stock sample" of at least 30 cc. in one container. All "A" and "B" test samples shall be held at approximately 75° F. under Branch lock until used. All other samples shall be held under Branch lock at 35° to 45° F.

§ 118.34 Phenolization. Simultaneous virus blood which has been thoroughly mixed after withdrawal of the purity test sample and test sample A shall have added to it a sufficient quantity of a 5-percent solution of phenol so that the virus will contain one-half of 1-percent phenol by volume. This phenolization must be accomplished with accuracy and in a manner which will prevent undesirable changes in the product.

§ 118.35 Holding of simultaneous virus. Simultaneous virus which has been mixed and phenolized at licensed establishments as provided in Parts 101 to 122 of this chapter, together with the virus-stock sample, shall be held under Branch lock as provided under § 102.77 (c) of this chapter until the tests required by Parts 101 to 122 of this chapter have been completed and have shown the virus to be free from contamination: *Provided, however*, That simultaneous virus which will not reach its destination before the tests are concluded or which is exported to a foreign country may be released prior to the conclusion of said tests. If the test respecting simultaneous virus so released is declared unsatisfactory, the manufacturer shall immediately recall all of such product in order that it may be placed under Branch lock.

§ 118.36 Disposition of samples of simultaneous virus. At least one container of the stock sample of simultaneous virus shall be held at the licensed establishment unopened in the manner provided in § 102.77 (c) of this chapter for at least 3 months after the latest expiration date shown upon the labels affixed to the immediate or true containers of the product corresponding to the sample.

§ 118.37 Test animals. Two healthy calves, with mouths free from abrasions, as described in § 117.3 of this chapter, or three healthy pigs immunized by the simultaneous treatment against hog cholera for at least 14 days, shall be furnished for intravenous injection with the purity test sample. These animals shall be given veterinary inspection immediately before the test is begun. All animals used for the test-

ing of simultaneous virus shall be injected only under the supervision of an inspector and shall be marked as provided in the regulations. All test animals shall be given veterinary inspection as frequently as practicable during the test period to determine whether any symptoms or lesions of a vesicular or other disease develop.

§ 118.38 **Purity test of simultaneous virus.** Each of the animals selected for testing the purity of simultaneous virus at licensed establishments shall be injected with 15 cc. of the purity-test sample into either the auricular or the jugular vein within 1 day after the first virus in the batch is collected.

§ 118.39 **Holding test animals.** Animals inoculated for the purpose of determining the purity of simultaneous virus at licensed establishments as provided in § 118.38 shall be held under the observation of a Branch employee at least 7 days. Should foot-and-mouth disease appear in the United States the said animals shall be held under the observation of inspectors for at least 10 days.

§ 118.40 **Test and retest.** If none of the animals which are treated with hog-cholera virus as prescribed in § 118.38 manifests symptoms of any infectious, contagious, or communicable disease, or if only one animal develops hog cholera, the test will be declared "satisfactory for purity," and the product released for marketing: *Provided*, It is otherwise satisfactory under the provisions of the regulations. Should any of the animals in the test succumb or should more than one develop hog cholera, another test may be made as in the first instance, except that not less than 15 cc. of the phenolized virus shall be used for the inoculation of each animal.

§ 118.41 **Swine erysipelas.** Representative samples of each batch or serial of simultaneous virus shall be tested at licensed establishments in the following manner to determine its freedom from swine erysipelas (Erysipelothrix rhusiopathiae):

(a) Within 1 day after the first virus in a batch is collected, at least 1 cc. of test sample A shall be injected intramuscularly into each of three or more young pigeons or 0.2 cc. of such sample shall be injected subcutaneously into each of three or more suitable mice susceptible to swine erysipelas. These test animals and birds shall be held under the observation of an inspector for 10 or more days after being injected with the virus under test.

(b) Three or more days after phenolization of the batch of virus, at least 1 cc. of test sample B shall be injected intramuscularly into each of three or more young pigeons or 0.2 cc. of such sample shall be injected subcutaneously into each of three or more suitable mice susceptible to swine erysipelas. These test animals and birds shall be held under the observation of an inspector for 7 or more days after being injected with the virus under test.

(c) If all test animals or birds injected with test sample A survive for 10 days or more, and all test animals or birds injected with test sample B survive for 7 days or more, after injection, the batch or serial represented by the samples may be marketed if it otherwise conforms to the requirements of Parts 101 to 122 of this chapter.

(d) Should any of the inoculated animals or birds die during the test, the product shall not be released for marketing and the reserve 30 cc. sample shall be forwarded to the Branch.

(e) All animals or birds, after being once used in the tests provided in this section, shall be killed and their carcasses destroyed by incineration or tanking as provided in § 108.16 of this chapter. Also all virus blood and simultaneous virus which are contaminated with Erysipelothrix rhusiopathiae shall be destroyed in like manner.

§ 118.42 Marking "U. S. Released." Each immediate or true container of simultaneous hog-cholera virus produced at licensed establishments which has been tested and found not to be worthless, contaminated, dangerous, or harmful, may have a cap affixed which, if approved by the Chief, may bear the words "U. S. Released." These caps shall be affixed to the aforesaid containers only under the supervision of an inspector and shall be held under Branch lock except when needed for this purpose. No simultaneous virus shall be released for marketing unless and until all information required by the regulations has been affixed to the containers thereof under supervision of an inspector. All simultaneous virus on which the expiration date has expired shall be destroyed as prescribed in § 108.16 of this chapter.

§ 118.43 Expiration date. The expiration date placed on the label of each immediate or true container of simultaneous virus produced at licensed establishments shall be one of the following:

(a) A date within 90 days after the first blood in the batch was collected: *Provided*, That the simultaneous virus is stored and marketed in containers acceptable to the Branch.

(b) A date within 120 days after the first blood in the batch was collected when the product is marketed in containers described in § 118.3 and is to be exported to a foreign country and the containers thereof are labeled distinctively.

§ 118.45 Minimum dosage and use. Labels affixed to or used in connection with each immediate or true container of simultaneous virus produced at licensed establishments shall bear a dosage table in which the doses recommended are not less than those appearing in the following table:

Weight:	*Minimum dose (cc.)*
Pigs weighing 45 pounds or less	1
Pigs weighing more than 45 pounds	2

Each label shall bear instructions to use the virus only with anti-hog-cholera serum.

PART 119—ANTI-HOG-CHOLERA SERUM

GENERAL REQUIREMENTS

Sec.

HYPERIMMUNE HOGS

ANTI-HOG-CHOLERA SERUM PREPARATION PROCEDURE

TESTING ANTI-HOG-CHOLERA SERUM

GENERAL REQUIREMENTS

§ 119.1 Supervision of production of anti-hog-cholera serum. No operation incident to the production of anti-hog-cholera serum at a licensed establishment shall be conducted without the knowledge or supervision of an inspector. The licensee shall notify the inspector in charge or the supervising inspector a reasonable time in advance whenever any such operations, including overtime work, are to be conducted in the licensed establishment.

§ 119.2 Production principle. Pigs that develop hog cholera of a well-marked and progressive type attended with progressively abnormal temperatures produce hog-cholera virus of high virulence, and when hogs properly immunized against hog cholera for a sufficient length of time are injected intravenously with massive quantities of such virus their blood serum possesses superior protective properties against hog cholera. Therefore, the facts should form the basis of all methods of producing anti-hog-cholera serum and hog-cholera virus as well as of all the regulations governing their production.

HYPERIMMUNE HOGS

§ 119.3 Required period of immunity. Anti-hog-cholera serum shall be derived at licensed establishments only from hyperimmune hogs which have been immune to hog cholera for at least 90 days prior to hyperimmunization.

§ 119.4 Health and weight when hyperimmunized. Hogs which are used to produce anti-hog-cholera serum at licensed establishments shall be healthy at the time of hyperimmunization, and this fact shall be determined by a thorough veterinary inspection. The weight of each animal in a given group shall be determined and recorded accurately by the licensee before hyperimmunization of the group.

§ 119.5 Dosage of virus. All hogs which are used to produce anti-hog-cholera serum at licensed establishments shall receive, for hyperimmunization, a single intravenous injection of at least 5 cc. of hog-cholera virus for each pound of the animal's weight when injected.

§ 119.6 Temperatures before bleeding. The temperatures of the hogs in each group or lot used to produce anti-hog-cholera serum at licensed establishments shall be determined under normal handling conditions and recorded accurately by the licensee either on the afternoon before, or on the day of, bleeding and at such other times as the inspector may require. There shall be provided clean, light quarters equipped with a satisfactory chute and all other facilities for expediting temperature taking and veterinary inspection.

§ 119.7 Inspection before bleeding. All hogs which are used to produce anti-hog-cholera serum at licensed establishments shall be subjected to a thorough veterinary inspection before each bleeding. Groups containing any hogs that are lame or otherwise suspected of being affected with a vesicular disease shall be given special examination for vesicles and the like after thorough cleansing of their feet, including examination of the coronary bands, snouts, and lips. Only those hogs which are found to have a temperature of less than 104° F. and are free from any infectious, contagious, or communicable diseases or other abnormal conditions shall be bled for serum. No hyperimmune hog in a lot or group of like origin having a significant number of high temperatures or showing other abnormalities indicative of an infectious or communicable disease shall be subjected to bleeding until such conditions of the lot or group as a whole no longer exist.

§ 119.8 Bleeding and examination. (a) Anti-hog-cholera serum shall be derived at licensed establishments only from hyperimmune hogs which have been subjected to not more than four successive bleedings, except that additional bleedings may be authorized by the Chief in emergencies.

The first bleeding shall take place not earlier than the eleventh day after hyperimmunization; subsequent bleedings shall not take place more frequently than once in 7 days; and the last bleeding shall be made on a date not later than 40 days after hyperimmunization: *Provided*, That, in emergencies, final bleeding may be deferred when specifically authorized by the Chief.

(b) Autopsies shall be performed at licensed establishments on hyperimmune hogs that succumb in order to obtain, if possible, information as to the cause of death. Employees of the licensed establishment, under the supervision of an inspector shall perform the labor incident to these examinations.

(c) Anti-hog-cholera serum derived at licensed establishments from final bleedings shall be kept separate from other serum until it has been determined by post mortem examinations that the hog from which the serum is derived was not so affected with any infectious, contagious, or communicable disease or in such condition as to render the serum worthless, contaminated, dangerous, or harmful.

§ 119.9 Constitutional symptoms. Anti-hog-cholera serum derived at licensed establishments from hogs which, after hyperimmunization, manifest symptoms indicative of an affection of a constitutional character other than those usually observed immediately following hyperimmunization shall not be mixed with other serum, unless after due consideration of the prevailing conditions, this action is permitted by a veterinary inspector. Such serum, if collected only from hogs as prescribed in § 119.8, may be prepared separately and tested as prescribed in the regulations and if, as a result of these tests, the product is found satisfactory, it may be marketed. Otherwise, the serum shall be destroyed as provided in § 108.16 of this chapter under the supervision of an inspector.

§ 119.10 Post mortem examination. (a) All hogs from which anti-hog-cholera serum is derived at licensed establishments shall be subjected, after final bleeding, to a thorough post mortem examination by an inspector. If, as a result of such inspection, it is found that any hog is so affected with any infectious, contagious, or communicable disease or is in such condition as to render the serum worthless, contaminated, dangerous, or harmful, the serum collected from such hog shall be destroyed by the licensee, as provided in § 108.16 of this chapter under the supervision of an inspector.

(b) If serum-producing hogs at a licensed establishment become exhausted as a result of tail bleeding, dressing of the animals may be permitted provided they are given veterinary inspection immediately before throat bleeding and provided the animals bleed properly. The carcasses of such hogs may be dressed for food if disposition thereof is made in accordance with the meat inspection regulations (9 CFR Chapter I, Subchapter A, as amended). The blood of such animals may be used for serum if the tail and throat bleeding operations are such that no more time elapses between tail bleeding and throat bleeding than is necessary for removing the animals from the tail-bleeding station and restraining them at a regular throat-bleeding station.

ANTI-HOG-CHOLERA SERUM PREPARATION PROCEDURE

§ 119.20 Heating; time and conditions. All anti-hog-cholera serum produced at licensed establishments shall be heated under the supervision of an inspector in such a manner as to subject the product and the entire container thereof to a temperature of 58.5° C. for 30 minutes with a tolerance of 0.5° above and below that temperature, by methods prescribed by the Chief.

§ 119.21 Heating containers. Metal containers of a capacity not to exceed 50 liters shall be used in heating anti-hog-cholera serum at licensed establishments. Such containers shall be equipped with satisfactory agitators, and facilities for cooling and preserving the product shall also be provided. All serum shall be handled prior to heating so that practically all "foam" is eliminated before beginning the heating process and shall be properly agitated while being heated, cooled, and preserved. Each container of serum at time of heating shall be so submerged that the water line in the bath will be at least 2 inches above the upper surface of the lid. No container or other equipment intended for heating, cooling, preserving, and storing serum shall be used unless it is acceptable to the inspector in charge.

§ 119.22 Heating and cooling; instructions. The temperature of the bath in which serum is heated at licensed establishments shall not be permitted to exceed 62° C. The temperature of the serum shall be reduced as rapidly as possible to 15° C. or lower after heating. The temperatures of the serum and the water in the bath shall be accurately determined and recorded by the use of automatic recording

thermometers. A separate recording thermometer shall be used for each container of serum during the heating and cooling operations. Such parts of heating and cooling equipment as it may be necessary to seal to insure that actual temperatures of the product and the water bath are properly recorded shall be sealed effectively by an inspector. Bulbs and other parts of thermometers which are placed within the serum container shall be submerged in a 5-percent phenol solution, or substitute permitted by the Chief, at all times when not in use for taking temperatures.

§ 119.23 **Instructions for preparation of anti-hog-cholera serum**—(a) **Definitions.** When used in this section, the following terms shall be construed to have the meanings hereby assigned.

(1) **Group number.** The number used to identify a group of hyperimmune hogs not in excess of 175, the blood of which is clarified and identified as one lot or as a fraction of a lot.

(2) **Class of bleeding.** The bleedings of hyperimmune hogs. First, second, third, and throat or carotid bleedings shall be identified by the letters A, B, C, and D, respectively.

(3) **Working unit.** The net quantity of hyperimmune blood in each container used as a basis of clarification.

(4) **Preserved serum.** True serum and permitted clarifying solutions recovered in the centrifugation of hyperimmune blood, preserved in compliance with the regulations.

(5) **Completed serum.** A combination of the different classes of preserved serum mixed in batches in such proportions as will equalize the potency of said classes.

(6) **Finished serum.** Completed serum which is bottled, tested, and fully labeled for marketing.

(7) **Number.** The number of hyperimmunes in any group, subjected to bleeding, to supply blood of a given class.

(8) **Weight.** The total weight, at the time of hyperimmunization, of all the hogs in the group that are bled in each class.

(9) **Lot number.** The identification number of the preserved serum produced from blood collected from one or more groups consisting of a total of not more than 175 hyperimmune hogs.

(10) **Batch.** Preserved serum mixed in a single container as required by the regulations.

(11) **Division rate.** The proportion which the total quantity of preserved serum of each class of bleedings bears to the total quantity in a lot.

(12) **Remainder.** The unused preserved serum of all classes remaining after one or more batches have been prepared from a lot.

(b) **General provisions.** (1) The composition of each lot of anti-hog-cholera serum shall be recorded by the licensee on a form acceptable to the Chief.

(2) The average yield of blood per pound for each class of bleedings shall be entered in the hyperimmune record in connection with the weight for the class.

(3) The quantity of blood treated with clarifying solutions in a single container shall not exceed 25,000 cc. All clarifying solutions shall be added to the working unit.

(4) All of the preserved anti-hog-cholera serum produced from the blood collected from a given group of hogs shall be placed in the same lot.

(c) **Rules and factors for computing yields of anti-hog-cholera serum.** The following rules and factors shall be used by licensed establishments in computing yields of anti-hog-cholera serum. When defibrinated hyperimmune blood is used, the total quantities in the lot shall constitute the basis for making the following computations.

(1) To find the quantity of true serum in the lot, subtract the sum of the quantities of clarifying solutions and preserving solution from the total quantity of preserved serum.

(2) To find the percentage of true serum recovered from the defibrinated blood, divide the total quantity of true serum by the total quantity of defibrinated blood used.

(3) To find the maximum production permissible when the true serum recovered represents 73.04 percent or less of the defibrinated blood used, divide the total quantity of true serum by 0.88.

(4) To find the maximum production permissible when the true serum recovered represents more than 73.04 percent of the defibrinated blood, multiply the total quantity of defibrinated blood used by 0.83. In determining the concentration of phenol solution to be selected in preserving "Serum recovered (gross)" prepared from defibrinated blood, the following table shall be used:

Serum recovered (gross) compared with defibrinated blood	True serum recovered compared with defibrinated blood	Preserving solutions (phenol) required
Percent	*Percent*	*Percent*
77.4666	73.4666	7.5
78.85	74.85	10
82.0459	78.0459	50

The figures in such table show the maximum yields that may be preserved with the different solutions without exceeding 83 percent of the defibrinated blood used, provided the clarifying solutions are exactly 4 percent of this blood. The figures for "Serum recovered (gross)" will vary as the clarifying solutions are permitted to vary from 4 percent.

(5) To find the division rates for the different classes of bleedings, divide the preserved serum in each class by the total quantity of preserved serum in the lot. Each rate shall be expressed as a decimal fraction and contain either three or six figures. A division rate of three figures may only be used, provided the last three of six figures are regarded as 1 and added to the third figure when they represent 501, or more and disregarded when they represent 500, or less. For example, 0.195501 shall be recorded and used as 0.196 and 0.184500 shall be recorded and used as 0.184.

(6) To find the percentage of true serum in the completed serum of a lot, divide the total net quantity of true serum used by the total quantity of preserved serum mixed.

(7) To find the percentage of completed serum as compared with the total quantity of defibrinated blood, divide the total quantity of completed serum by the total quantity of defibrinated blood used.

(8) To find the total weight of hyperimmune hogs used or bled, find the combined weights taken at the time of hyperimmunization for the hogs actually bled for each class of bleedings.

(9) To find the yield of defibrinated blood per pound of hyperimmune hogs, divide the total quantity of defibrinated blood collected from each class of bleedings of hyperimmunine hogs by the total weight of the animals bled. The sum of these results for all bleedings combined will represent the yield of defibrinated blood per pound.

(10) To find the yield of completed serum per pound of hyperimmune hogs, divide the total quantity of completed serum by the total pounds of hyperimmune hogs used.

(d) **Preparing batches.** The following instructions shall be observed by licensed establishments in preparing batches of anti-hog-cholera serum:

(1) When not more than one batch of completed serum is to be prepared from the lot: Determine the net quantity of preserved serum mixed and the loss in handling.

(2) When two or more batches not to exceed 300,000 cc. each of completed serum equal or approximately equal in size are to be prepared from the lot: Divide the quantity of preserved serum of each class of bleedings in the lot by the number of batches that are to be prepared. The quotient will show the quantity of preserved serum of each class required for each batch. Proceed in the preparation of each batch as outlined in this section.

(3) When one or more batches of completed serum and a remainder are to be prepared from the lot: Determine the quantity of preserved serum of each class of bleedings required to make a batch of approximately 300,000 cc. of completed serum, and multiply the total quantity of preserved serum required by the division rate for each class. The results will show the quantity of preserved serum of each class required. Proceed with the preparation of the batch as outlined in this section. Proceed with the preparation of as many additional batches approximating 300,000 cc. each as may be possible from the lot as outlined in this section. The unused portions of a lot when they aggregate less than 300,000 cc. may be mixed together and tested and marketed as a batch, or shall be identified as "Remainder of Lot No. ____" and be made a part of the next batch mixed.

(4) When more than one batch of completed serum is to be prepared from the lot and a remainder is to be used: Determine the quantity of preserved serum of each class required to make a fraction of a batch of completed serum which, when added to the remainder, will approximate 300,000 cc., by subtracting from 300,000 cc., the quantity of preserved serum derived from the remainder. The difference will show the theoretical quantity of preserved serum that may be added to the remainder to make a batch of approximately 300,000 cc. of completed serum. Proceed with the preparation of the fraction of the batch as outlined in this section. Add the remainder to the completed fraction of the batch to find the quantity of completed serum in the batch. Proceed with the preparation of as

many additional batches approximating 300,000 cc. each as may be possible from the lot as outlined in this section.

(5) When only one batch of completed serum is to be prepared from the lot and a remainder is to be used: Prepare the fractional part of the batch as outlined in this section. Add the remainder to the fraction to find the quantity of completed serum in the batch.

(6) Batches larger than 300,000 cc.: Such batches shall be prepared by mixing in a single container all preserved serum derived from one or more properly identified whole groups totaling not more than 175 hogs.

§ 119.24 Batches; determination of quantity. Anti-hog-cholera serum which is to constitute a batch or portion thereof may be strained into a single container, after which the quantity should be accurately determined.

§ 119.25 Phenolization. (a) Anti-hog-cholera serum produced at licensed establishments shall have added thereto a sufficient quantity of a 7½ percent solution of phenol to make the completed serum consist one-half of 1 percent of phenol by volume: *Provided*, That either a 10 percent phenol solution or a solution containing equal parts by weight of phenol and ether may be used when yields or methods require this as a means to keep the total quantity of serum produced from a given quantity of blood within requirements of the regulations. When a 10 percent phenol solution is used, at least 10 percent of its volume shall be glycerin.

(b) To preserve serum properly, the following procedure shall be observed:

(1) When a 7.5 percent solution is used, divide the quantity of serum by 14.

(2) When a 10 percent solution is used, divide the quantity of serum by 19.

(3) When the phenol-ether solution, mentioned above, is used, divide the quantity of serum by 86.

(c) Phenolization of anti-hog-cholera serum must be accomplished with accuracy, and in a manner which will prevent the occurrence of undesirable changes in the product. In every case the concentration and quantity of each solution used in preserving the serum shall be recorded by the licensee.

§ 119.26 Mixing and holding. Anti-hog-cholera serum, prior to testing, at licensed establishments shall be thoroughly mixed in a single container into batches of not more than 300,000 cc. composed of proper proportions of the different classes of bleedings as provided in the regulations:

Provided, however, That larger batches may be prepared by mixing in a single container all serum derived from one or more properly identified whole groups of hyperimmune hogs totaling not more than 175 hogs. Until the serum is released by an inspector, it shall be held under Branch lock except when being processed.

§ 119.27 Samples. After a batch of anti-hog-cholera serum is thoroughly mixed in a single container, at a licensed establishment, a representative sample consisting of at least 300 cc. shall be collected in three containers of not less than 100 cc. each, to be known as the "serum test sample." This sample shall be taken, properly labeled, marked by an inspector, and held under Branch lock. One of the three containers shall be marked "stock sample" and held under Branch lock for at least 6 months after the latest expiration date shown on the labels affixed to the immediate or true containers of the serum of which this sample is a part.

§ 119.28 Disposition of samples. Unused samples of anti-hog-cholera serum prepared at licensed establishments on which the expiration date has passed 6 months previously may be labeled and marked in the regular manner, provided this procedure is approved by the inspector in charge and the serum is at that time tested and found satisfactory for potency and purity, and such labeling and marking is done within 3 years after the oldest serum in the batch is collected. When these conditions are not met, and it is desired to market the serum, the samples shall be mixed and assigned a serial number. This mixture may be tested alone or it may be mixed with other untested serum and tested as prescribed in the regulations: *Provided*, That the samples shall not constitute more than 50 percent of the serum contained in the final mixture. The expiration date to be affixed to the containers of mixtures of unused samples shall not exceed 1 year from the date of conclusion of a satisfactory test for potency.

TESTING ANTI-HOG-CHOLERA SERUM

§ 119.50 Tests required. All anti-hog-cholera serum produced at licensed establishments shall be tested for purity and potency as prescribed by the regulations. Special tests may be authorized by the Chief under § 114.2 of this chapter.

§ 119.51 Test pigs. Licensees shall furnish all pigs used in testing anti-hog-cholera serum. Eight healthy pigs, susceptible to hog cholera and weighing not less than 40 pounds

nor more than 115 pounds each, shall be used for testing each batch of serum consisting of 300,000 cc. or less. Batches consisting of more than 300,000 cc. shall be tested on 11 such pigs instead of 8. The inspector supervising the test shall indicate the pigs which shall receive anti-hog-cholera serum with hog cholera virus and those which shall receive the virus only.

§ 119.52 Dosage in tests. Each pig furnished at licensed establishments for testing anti-hog-cholera serum shall be injected with 2 cc. of hog-cholera virus. Three pigs in each test shall receive no serum and shall serve as controls. The remaining pigs in the test shall receive 15 cc. each of the serum to be tested, except that pigs weighing more than 90 pounds may receive 20 cc. The virus and serum injections shall be made simultaneously, the virus being injected in the left axillary space, and the serum in the right. Each of the pigs in the test shall be injected with virus of the same serial number, the virus to be selected and administered by an inspector.

§ 119.53 Handling test pigs. All surviving pigs used for testing a batch of serum at a licensed establishment shall be subjected to the same conditions throughout the test period and shall be held in a single pen or inclosure throughout this period, except that when it is evident that a particular serum test will be declared "no test" or "unsatisfactory for potency," the test pigs, with the permission of the supervising inspector, may be removed from the original test pen and placed with other pigs of the same class in a common pen for the purpose of releasing pen space for other tests.

§ 119.54 Observation and holding period; test pigs. The period for holding surviving pigs under the observation of an inspector, at licensed establishments, while being used for testing the potency and purity of anti-hog-cholera serum as described in the regulations, shall be not less than 14 days immediately following their inoculation for this purpose and as much longer as the inspector in charge deems necessary to render proper judgment on the results of the tests. Such pigs shall not be removed from the test unless and until released by the supervising inspector, who will permit their removal only after they have served their purpose in the prescribed tests.

§ 119.55 Temperatures; test pigs. The temperature of each pig used in a test of anti-hog-cholera serum at licensed establishments shall be taken and recorded shortly before

such test is started. Temperatures of control pigs and "slow" or sick serum-treated pigs in serum tests, except known "unsatisfactory tests" and "no tests," shall be taken and recorded daily throughout the test period on regular work days and such other days as the inspector in charge may direct when it appears desirable for proper disposition of the test. When pigs in tests do not manifest "slowness" or symptoms of sickness, their temperatures need not be taken except when required by the inspector in charge to determine more accurately the physical condition of the animals under observation.

§ 119.56 Virus required. Simultaneous virus or its equivalent, as described in § 118.3 of this chapter, in sufficient quantities to meet the needs shall be furnished by licensed establishments for use as the inspector in charge may deem advisable for inoculating pigs in serum tests. Hog-cholera virus furnished by the Branch shall be used in inoculating pigs in tests whenever the inspector in charge deems this procedure advisable, and whenever conditions in previous tests of any batch of serum have indicated some deficiency in either the virus or serum used.

§ 119.57 Principle for judging results of tests. The following principle and the rules in § 119.58 are to be used as guides in judging the results of serum tests at licensed establishments:

It is practically impossible in many cases to differentiate accurately between hog cholera, pneumonia, and other conditions affecting hogs without the aid of an autopsy as well as laboratory techniques and experiments to determine the causative agent responsible for the condition. Therefore, when healthy pigs are selected for testing anti-hog-cholera serum any abnormal condition in the pigs subsequent to their inoculation shall be regarded as due either to the virus used or, in serum-treated pigs, to the fact that the serum does not protect, unless the condition is definitely known or can be shown to be due to some other cause.

§ 119.58 Rules for judging results of test. The following rules shall apply at licensed establishments in judging anti-hog-cholera serum tests described in the regulations.

(a) **Control pigs.** The purpose of control pigs in serum tests is to furnish information as to the virulence of the virus used for inoculating the animals and to indicate whether the pigs furnished are susceptible to hog cholera. As an aid in

determining the fulfillment of this purpose the following conditions shall obtain.

(1) At least two of the control pigs shall become visibly sick of hog cholera subsequent to the third day of the test period or the fourth day, if the third day falls on a Sunday or holiday, and within 7 days after the test is begun.

(2) At least two of the control pigs which become sick as described in subparagraph (1) of this paragraph shall manifest well-marked and increasingly grave symptoms of hog cholera attended with progressively abnormal temperatures common to the acute type of this disease.

(3) At least two of the control pigs which become sick as described in subparagraphs (1) and (2) of this paragraph shall show lesions upon post mortem examination sufficient for the inspector to make a positive diagnosis of hog cholera, when considered with the ante mortem behavior of these animals.

(b) **Test; conditions under which serum to be declared "satisfactory for potency."** Serum will be declared "satisfactory for potency" when at least two of the control pigs react as described in paragraph (a) of this section and either of the following conditions obtains:

(1) All the serum-treated pigs remain well throughout the test period.

(2) One or more of the serum-treated pigs become visibly sick after the time of inoculation and all fully recover before the test animals are released by the inspector. Such sick pigs, however, will not be regarded as fully recovered until they have been in an apparently normal condition for at least 3 consecutive days.

(c) **Test; conditions under which serum to be declared "unsatisfactory for potency."** Serum will be declared "unsatisfactory for potency" when at least two of the control pigs react as described in paragraph (a) of this section and the following condition obtains:

One or more of the serum-treated pigs become visibly sick subsequent to the third day after the time of inoculation, or the fourth day, if the third day falls on a Sunday or holiday, and fail to recover fully before the test animals are released by the supervising inspector.

(d) **Test; conditions under which serum to be declared "no test for potency."** Serum will be declared "no test for potency" when any one of the following conditions obtains,

but such action will not prevent a retest under the provisions of the regulations:

(1) One or more of the serum-treated pigs become visibly sick on or before the third day after the time of inoculation, or the fourth day, if the third day falls on a Sunday or holiday, and fail to recover within the test period.

(2) Two or more of the control pigs become visibly sick on or before the third day after the time of inoculation, or the fourth day, if the third day falls on a Sunday or holiday.

(3) Two or more of the control pigs do not manifest symptoms of hog cholera as described in paragraph (a) of this section.

(4) Two or more of the control pigs do not show lesions of hog cholera upon post mortem examination as described in paragraph (a) of this section.

(5) Two or more of the control pigs manifest symptoms of hog cholera within 7 days as described in paragraph (a) of this section but do not become sick to the degree described in said paragraph.

(6) Any of the serum-treated pigs develop, during the test period, symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is not caused by the serum used.

(7) A condition obtains in any of the test pigs which is not otherwise covered in this section.

(e) **Test; when serum to be declared "satisfactory for purity."** Serum will be declared "satisfactory for purity" when the following condition obtains:

Not more than one of the serum-treated pigs in a test develops an abscess at the site of the serum injection and no symptoms of any infectious, contagious, or communicable disease other than hog cholera are manifested by any of the animals in the test.

(f) **Test; conditions under which serum to be declared "unsatisfactory for purity."** Serum will be declared "unsatisfactory for purity" when either of the following conditions obtains:

(1) Abscesses which are not definitely known to be due to causes other than the serum used develop at the sites of the serum injections in more than one of the serum-treated pigs.

(2) During the test period any of the serum-treated test pigs develop symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is due to the serum used.

(g) **Test; conditions under which serum to be declared "no test for purity."** Serum will be declared "no test for purity" when any one of the following conditions obtains, but such action will not prevent a retest under the provisions of the regulations.

(1) Two or more of the serum-treated pigs succumb within 14 days after the time of inoculation.

(2) Any of the serum-treated pigs develop, during the test period, symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is not caused by the serum used.

(3) A condition obtains in any of the test pigs which is not otherwise covered in this section.

§ 119.59 Retests when serum found "unsatisfactory for potency." When a test of anti-hog-cholera serum, prepared at a licensed establishment, has shown it to be "unsatisfactory for potency," the serum may be tested again as prescribed in § 119.51. Should this retest show the serum to be "unsatisfactory for potency" it may be so retested again, and if still found "unsatisfactory for potency" the serum shall be destroyed or otherwise disposed of as prescribed by the Chief.

§ 119.60 Tests for purity. Should abscesses develop at the sites of the serum inoculations in any of the pigs used at licensed establishments for testing serum as provided in this part, the following rules shall apply:

(a) Judgment of the results of tests made on pigs to determine the potency of the anti-hog-cholera serum will be rendered irrespective of conditions found which are regarded as an index to the purity of the product.

(b) If anti-hog-cholera serum upon testing is declared "satisfactory for purity," and it is found necessary to subject the batch of serum to a retest to determine its potency, judgment concerning the purity of the product shall be based on the first test unless evidence is found subsequent to such test which indicates that the serum is contaminated.

§ 119.61 Retests for purity. (a) When anti-hog-cholera serum prepared at a licensed establishment has once been found "unsatisfactory for purity," as defined in § 119.58, it may be tested again for purity on eight pigs, provided each pig receives a single injection, in the axillary space, of at least 20 cc. of the product.

(b) When anti-hog-cholera serum produced at a licensed establishment has twice been found "unsatisfactory for

purity," as defined in § 119.58, but is "satisfactory for potency," as provided in § 119.58, it may be tested again to ascertain whether it is contaminated with pus-producing organisms by treating 50 hogs on the premises of the licensed establishment. The serum shall be administered under the supervision of an inspector, and each hog treated shall receive a single injection, in the axillary space, of not less than 25 cc. of the product to be tested. Serum tested as provided in this paragraph shall be destroyed or otherwise disposed of or used as prescribed by the Chief.

§ 119.62 Purity test animals; holding period. Animals used for testing serum as provided in § 119.61 at licensed establishments shall be held under the supervision of an inspector for at least 14 days, and be carefully examined at the sites of inoculations to determine whether the serum has caused abscess formation.

§ 119.63 Minimum dosage. When anti-hog-cholera serum produced at licensed establishments, upon testing as provided in Parts 101 to 122 of this chapter, is found "satisfactory for potency" and "satisfactory for purity," the product may be marketed if it is recommended for use in doses not less than those appearing in the following table:

Weight:	*Minimum dose (cc.)*
Suckling pigs	20
Pigs 20 to 40 pounds	30
Pigs 40 to 90 pounds	35
Pigs 90 to 120 pounds	45
Hogs 120 to 150 pounds	55
Hogs 150 to 180 pounds	65
Hogs 180 pounds and over	75

§ 119.64 Marking anti-hog-cholera serum "U. S. Released." Each immediate or true container of anti-hog-cholera serum produced at a licensed establishment, and which has been tested and found not to be worthless, contaminated, dangerous, or harmful may have a cap affixed which, if approved by the Chief, may bear the words "U. S. Released." These caps shall be affixed to the aforesaid containers only under the supervision of an inspector and shall be held under Branch lock except when needed for this purpose.

§ 119.65 Expiration date. The expiration date shown on labels of anti-hog-cholera serum produced at licensed establishments shall not exceed 3 years from the date on which

the first serum of the batch is collected, except as provided in § 119.66.

§ 119.66 Extension of expiration date. Should the expiration date of any batch of anti-hog-cholera serum produced at licensed establishments expire before the serum is used, the serum may be retested, and if found "satisfactory for potency" and "satisfactory for purity," as defined in § 119.58 (b) and (e), the expiration date may be extended for 1 year from the date of conclusion of the retest for potency. Should a batch of anti-hog-cholera serum not be found "satisfactory for potency" or "satisfactory for purity" before the expiration of 3 years from the date of collection of the oldest serum in the batch, or should it not be so found in time to allow it to be used before the expiration of said 3 years, the expiration date will be limited to 6 months from the date of conclusion of a satisfactory test for potency.

§ 119.67 Requirements for filling and labeling. No immediate or true container of anti-hog-cholera serum shall be filled in whole or in part, and no label shall be affixed to such a container at licensed establishments, except under the supervision of an inspector.

§ 119.68 Conditions for release and removal. Anti-hog-cholera serum shall not be removed from the premises of a licensed establishment unless it has been prepared as required by the regulations, and no such serum shall be released for marketing unless and until all the information required by the regulations has been affixed to the containers thereof under the supervision of an inspector.

PART 121—ADMISSION OF BIOLOGICAL PRODUCTS AND MATERIALS TO LICENSED ESTABLISHMENTS

Sec.

§ 121.1 Requirements re admission of biological products, etc., to licensed establishments. Except as specifically authorized by the regulations, no biological product which has not been prepared, handled, stored, and marked in accordance with the regulations and no biological product which is worthless, contaminated, dangerous, or harmful shall be brought onto the premises of any licensed establishment.

§ 121.2 Branch virus and serum. Hog-cholera virus and anti-hog-cholera serum prescribed by the Branch will be admitted to licensed establishments for use as prescribed in the regulations or as may be approved by the Chief.

§ 121.3 Virus from outbreaks. Hog-cholera virus procured from outbreaks of hog cholera on farms that are free from other communicable diseases will be admitted to licensed establishments by the inspector in charge when requested by the licensee for use in propagating a new strain of virus for inoculating purposes. Before such virus is used in the production of simultaneous virus or hyperimmunizing virus, it shall be injected into pigs weighing from 40 to 90 pounds to determine whether the purity and virulence of the product are satisfactory. The virus shall be passed through pigs, as provided in the regulations until its virulence and purity are satisfactory; otherwise, the product shall be destroyed as provided in § 108.16 of this chapter.

§ 121.4 Transportation between licensed establishments. Anti-hog-cholera serum and hog-cholera virus, spleens, and other organs, collected in licensed establishments, and suitable for use under the regulations, may be transported from one licensed establishment to another or between units of the same establishment provided these products are properly packed. Such products and materials must be packed or iced so that a proper temperature will be maintained during transportation. The containers shall be sealed by an authorized inspector, and such seals shall be broken only by such an inspector at the point of destination; otherwise, the products and materials shall be refused admission at the licensed establishment to which transported.

PART 122—ORGANISMS AND VECTORS

Sec.

§ 122.1 Permits required. No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof: *Provided*, That no permit shall be required under this section for importation of organisms for which an import permit has been issued pursuant to Part 102 of this

chapter or for transportation of organisms produced at establishments licensed under Part 102 of this chapter. As a condition of issuance of permits under this section, the permittee shall agree in writing to observe the safeguards prescribed by the Chief for public protection with respect to the particular importation or transportation. Permits shall be numbered and shall be in the following form:

UNITED STATES VETERINARY PERMIT NO._____

ORGANISMS OR VECTORS

*Washington, D. C.*_____

Under authority of Act of Congress approved February 2, 1903 (32 Stat. 792, 21 U. S. C. 111) and Act of Congress approved March 4, 1913 (37 Stat. 832–833, 21 U. S. C. 151–158), _____ is hereby authorized, so far as the jurisdiction of the Department of Agriculture is concerned, to (import or transport) _____ from _____ to_____ via _____.

This permit is issued under authority contained in § 121.1, Subchapter E, Chapter I, Title 9 CFR, and on the basis of the signed agreement of the permittee to use the organisms and their derivatives, or vectors, only for the purpose specified therein, and to dispose of them as directed by the Animal Inspection and Quarantine Branch.

_____

Secretary of Agriculture

Countersigned:

_____

Chief, Animal Inspection and Quarantine Branch

§ 122.2 Application for permit. The Secretary may issue, at his discretion, a permit as specified in § 121.1 when proper safeguards are set up as provided in § 122.1 to protect the public. Application for such a permit shall be made in advance of shipment, and each permit shall specify the name and address of the consignee, the true name and character of each of the organisms or vectors involved, and the use to which each will be put.

§ 122.3 Suspension or revocation of permits. (a) Any permit for the importation or transportation of organisms or vectors issued under this part may be formally suspended or revoked after opportunity for hearing has been accorded the permittee, as provided in Part 123 of this chapter, if the Secretary finds that the permittee has failed to observe the safeguards and instructions prescribed by the Chief with respect to the particular importation or transportation or that such importation or transportation for any other reason may result in the introduction or dissemination from a foreign country into the United States, or from one State, Terri-

tory or the District of Columbia to another, of the contagion of a contagious, infectious or communicable disease of animals (including poultry).

(b) In cases of wilfulness or where the public health, interest or safety so requires, however, the Secretary may without hearing informally suspend such a permit upon the grounds set forth in paragraph (a) of this section, pending determination of formal proceedings under Part 123 of this chapter for suspension or revocation of the permit.

(37 Stat. 832, sec. 2, 32 Stat. 792; 21 U. S. C. 151–158, 111)

PART 123—RULES OF PRACTICE

Sec.

AUTHORITY: §§ 123.1 to 123.19 issued under 37 Stat. 832, sec. 2, 32 Stat. 792; 21 U. S. C. 151–158, 111.

§ 123.1 Definitions. The following words, when used in the rules in this part, shall be construed, respectively, to mean:

(a) **Virus-Serum-Toxin Act.** The act of Congress of March 4, 1913, 37 Stat. 832–833, 21 U. S. C. 151–158.

(b) **Section 2 of the act of February 2, 1903.** Section 2 of the act of Congress of February 2, 1903, 32 Stat. 791, as amended, 21 U. S. C. 111.

(c) **Regulations.** The provisions in Parts 101 through 122 of this subchapter.

(d) **Department.** The United States Department of Agriculture.

(e) **Branch.** The Animal Inspection and Quarantine Branch of the Department.

(g) **Secretary.** The Secretary of the Department or any other officer or employee of the Department to whom authority has heretofore lawfully been delegated, or may hereafter lawfully be delegated, to act in his stead.

(h) **Chief.** The Chief of the Branch or any other officer or employee of the Branch to whom authority has heretofore lawfully been delegated, or may hereafter lawfully be delegated, to act in his stead.

(i) **Licensee.** A person to whom a license to manufacture biological products has been issued under the regulations.

(j) **Permittee.** A person to whom a permit to import or transport biological products or organisms or vectors has been issued under the regulations.

(k) **Hearing clerk.** The hearing clerk, United States Department of Agriculture, Washington, D. C.

(l) **Examiner.** Any examiner in the Office of Hearing Examiners, United States Department of Agriculture.

(m) **Complainant.** The party upon whose order to show cause a formal proceeding is instituted.

(n) **Respondent.** The party proceeded against.

(o) **Hearing.** That part of a proceeding under the rules in this part which involves the submission of evidence, either orally or in writing.

(p) **Examiner's report.** The examiner's report to the Secretary, including the examiner's proposed (1) findings of fact and conclusions with respect to all material issues of fact, law, or discretion, as well as the reasons or basis therefor, (2) order, and (3) rulings on findings, conclusions, and orders submitted by the parties.

(q) **Biological products.** All viruses, serums, toxins, and analogous products, such as antitoxins, vaccines, tuberculins, malleins, live microorganisms, killed microorganisms, and products of microorganisms, intended for use in the treatment of domestic animals, including the diagnosis or detection of diseases of such animals.

(r) **Organisms.** All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry).

(s) **Vectors.** All animals (including poultry), such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens,

dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

§ 123.2 Proceedings to which rules apply. The rules of practice in this part shall apply to formal proceedings for the suspension or revocation of licenses or permits under the regulations and, insofar as appropriate, to proceedings against a representative of any party under § 123.10 (c) (1).

§ 123.3 Procedure prior to institution of formal proceedings. In all cases except those involving wilfulness or in which the public health, interest, or safety otherwise requires, prior to the institution of a formal proceeding under this part, the Chief, in an effort to effect an amicable or informal adjustment of the matter, shall give written notice to the licensee, permittee, or other person involved, of the facts or conduct which appear to warrant institution of such a proceeding and shall afford such person an opportunity, within a reasonable time fixed by the Chief, to demonstrate or achieve compliance with the applicable requirements of the Virus-Serum-Toxin Act, section 2 of the act of February 2, 1903, and the regulations. In any case in which compliance is demonstrated or achieved, no formal proceeding shall be instituted.

§ 123.4 Stipulations and consent orders—(a) **Stipulation of compliance.** At any time prior to the issuance of the order to show cause in any proceeding, the Secretary, in his discretion, may enter into a stipulation with the prospective respondent, whereby the latter admits the material facts and agrees to discontinue the acts or practices complained of. Such stipulations shall be admissible as evidence of such acts and practices in any subsequent proceeding against such person before the Secretary.

(b) **Consent order.** At any time after the issuance of the order to show cause and prior to the hearing in any proceeding, the Secretary, in his discretion, may allow the respondent to consent to an order. Upon a record composed of the order to show cause and a stipulation made for the record by the respondent consenting to the order and admitting at least those facts necessary to the Secretary's jurisdiction, the Secretary may enter the order consented to by the respondent, which shall have the same force and effect as an order made after oral hearing.

§ 123.5 **Order to show cause**—(a) **Filing, service, and contents.** If a case is not disposed of under the procedure described in § 123.3 or § 123.4 (a), the Chief may institute formal proceedings by filing an order to show cause, in triplicate, with the hearing clerk, who promptly shall serve a true copy thereof upon the respondent, as provided in § 123.19 (b). The order to show cause shall be addressed to the respondent, shall state briefly and clearly the allegations of fact which constitute a basis for the proceeding, and the legal authority and jurisdiction under which the proceeding is instituted, and shall specify with particularity the matters in issue. The order to show cause shall not include charges, implied charges, or requirements phrased generally in the words of the Virus-Serum-Toxin Act or the act of February 2, 1903, but such acts may be identified and quoted or used in preliminary recitals.

(b) **Amendments.** At any time prior to the close of the hearing, the order to show cause may be amended, but, in case of an amendment adding new provisions, the hearing shall, at the request of the respondent, be adjourned for a period not exceeding 15 days. Amendments subsequent to the first amendment or subsequent to the filing of an answer by the respondent may be made only with leave of the examiner or with the written consent of the adverse party.

(c) **Docketing.** Each proceeding immediately following its institution shall be assigned a docket number by the hearing clerk, and thereafter the proceeding shall be referred to by such number.

§ 123.6 **Answer**—(a) **Filing and service.** Within 20 days after service of the order to show cause, the respondent shall file, in triplicate, with the hearing clerk, an answer, signed by the respondent or his attorney: *Provided*, That the Secretary may order that the hearing be held without answer or other pleading. The answer shall be served upon the complainant, and any other party of record, in the manner provided in § 123.19 (b).

(b) **Contents; failure to file answer.** (1) The answer shall (i) contain a statement of the facts which constitute the grounds of defense, and shall specifically admit, deny, or explain each of the allegations of the order to show cause unless respondent is without knowledge, in which case the answer shall so state; or (ii) state that the respondent admits all of the allegations of the order to show cause. The answer may contain a waiver of hearing.

(2) Failure to file an answer to or plead specifically to any allegation of the order to show cause shall constitute an admission of such allegation.

(c) **Admission of facts.** The admission, in the answer or by failure to file an answer, of all the material allegations of fact contained in the order to show cause shall constitute a waiver of hearing. Upon such admission of facts, the examiner, without further investigation or hearing, shall prepare his report, in which he shall adopt as his proposed findings of fact the material facts alleged in the order to show cause. Unless the parties have waived service of the examiner's report, it shall be served upon them in the manner provided in § 123.19 (b). The parties shall be given an opportunity to file exceptions to the report, to file briefs in support of such exceptions, and to make oral argument thereon before the Secretary. Any request to make oral argument before the Secretary must be filed in the manner and within the time provided in § 123.15.

§ 123.7 Motions and requests. Any motion will be entertained except a motion to dismiss on the pleadings. All motions and requests shall be filed in triplicate with the hearing clerk, except that those made during the course of an oral hearing may be filed with the examiner or may be stated orally and made a part of the transcript. The examiner is authorized to rule upon all motions and requests filed or made prior to the filing of his report with the hearing clerk as hereinafter provided. The Secretary will rule upon all motions and requests filed after that time. The submission of any motion, request, objection, or other question to the Secretary prior to the time when the examiner's report is filed with the hearing clerk shall be in the discretion of the examiner.

§ 123.8 Examiners—(a) Assignment. No examiner shall be assigned to serve in any proceeding who (1) has any pecuniary interest in any matter or business involved in the proceeding, (2) is related within the third degree by blood or marriage to any party to the proceeding, or (3) has participated in the investigation preceding the institution of the proceeding, or in the determination that it should be instituted, or in the preparation of the order to show cause, or in the development of the evidence to be introduced therein.

(b) **Disqualification.** (1) Any party may file with the hearing clerk a timely affidavit of disqualification of the examiner, which shall set forth with particularity the grounds of alleged disqualification. After such investigation or hear-

ing as the Secretary shall deem necessary, he may find the affidavit without merit or may direct that another examiner be assigned to the proceeding. Where the affidavit is found without merit, the affidavit, any record made thereon, and the finding and order of the Secretary shall be made a part of the record.

(2) An examiner shall ask to be withdrawn from any proceeding in which he deems himself disqualified for any reason.

(c) **Conduct.** The examiner shall conduct the proceeding in a fair and impartial manner, and save to the extent required for the disposition of ex parte matters as authorized by law, he shall not consult any person or party on any fact in issue unless upon notice and opportunity for all parties to participate.

(d) **Powers.** Subject to review by the Secretary as provided elsewhere in this part, the examiner, in any proceeding assigned to him, shall have power to: (1) Rule upon motions and requests; (2) set the time and place of hearing, adjourn the hearing from time to time and change the time and place of hearing; (3) administer oaths and affirmations and take affidavits; (4) examine witnesses and receive evidence; (5) take or order, under the facsimile signature of the Secretary, the taking of, depositions; (6) admit or exclude evidence; (7) hear oral argument on facts or law; and (8) do all acts and take all measures necessary for the maintenance of order and the efficient conduct of the proceeding.

(e) **Who may act in absence of the examiner.** In case of the absence of the examiner or his inability to act, the powers and duties to be performed by him under this part in connection with a proceeding assigned to him may, without abatement of the proceeding unless otherwise directed by the Secretary, be assigned to any other examiner.

§ 123.9 Prehearing conferences. In any proceeding in which it appears that such procedure will expedite the proceeding, the examiner, at any time prior to the commencement of the oral hearing, may request the parties or their counsel to appear at a conference before him to consider (a) the simplification of issues; (b) the necessity or desirability of amendments to pleadings; (c) the possibility of obtaining stipulations of fact and of documents which will avoid unnecessary proof; (d) the limitation of the number of expert or other witnesses; and (e) such other matters as may expedite and aid in the disposition of the proceeding. No

transcript of such conference shall be made, but the examiner shall prepare and file for the record a written summary of the action taken at the conference, which shall incorporate any written stipulations or agreements made by the parties at the conference or as a result of the conference. If the circumstances are such that a conference is impracticable, the examiner may request the parties to correspond with him for the purpose of accomplishing any of the objects set forth in this section. The examiner shall forward copies of letters and documents to the parties as the circumstances require. Correspondence in such negotiations shall not be a part of the record, but the examiner shall submit a written summary for the record if any action is taken.

§ 123.10 Oral hearing before examiner—(a) **Request for oral hearing.** Any party may request an oral hearing on the facts by including such request in the order to show cause or the answer or by a separate request in writing filed with the hearing clerk. Failure to request an oral hearing within the time allowed for the filing of the answer shall constitute a waiver of such hearing, and the party so failing to request an oral hearing will be deemed to have agreed that the proceeding may be decided upon a record formed under the shortened procedure provided in § 123.13. Waiver of oral hearing shall not be deemed to be a waiver of the right to make oral argument before the Secretary upon exceptions to the examiner's report. Such argument will be allowed in accordance with the provisions of § 123.15.

(b) **Time and place.** If and when the proceeding has reached the stage where an oral hearing is to be held, the examiner, giving careful consideration to the convenience of the parties, shall set a time and place for hearing and shall file with the hearing clerk a notice stating the time and place of hearing. If any change in the time or place of the hearing is made, the examiner shall file with the hearing clerk a notice of such change, which notice shall be served upon the parties, unless the change is made during an oral hearing and made a part of the transcript.

(c) **Appearances—(1) Representation.** In any proceeding under the regulations, the parties may appear in person or by counsel or other representative. The Chief, if represented by counsel, shall be represented by an attorney assigned by the Solicitor of the Department. Persons who appear as counsel or in any other representative capacity at a hearing must conform to the standards of ethical conduct

required of practitioners before the courts of the United States. Whenever the Secretary finds, after notice and opportunity for hearing, that a person, who is acting or has acted as counsel or other representative for another person in any proceeding before the Secretary, is unfit to act as such counsel or other representative, he will order that such person be precluded from acting as counsel or other representative in any proceeding under this part. The procedure in such case will be governed by the applicable provisions of the rules of practice in this part.

(2) **Failure to appear.** (i) If any party to the proceeding, after being duly notified, fails to appear at the hearing, he shall be deemed to have waived the right to an oral hearing in the proceeding. In the event that a party appears at the hearing and no party appears for the opposing side, the party who is present shall have an election whether to present his evidence, in whole or in part, in the form of affidavits or by oral testimony before the examiner.

(ii) Failure to appear at a hearing shall not be deemed to be a waiver of the right to be served with a copy of the examiner's report and to file exceptions and make oral argument before the Secretary with respect thereto, in the manner provided hereinafter.

(d) **Order of proceeding.** Except as may be determined otherwise by the examiner, the complainant shall proceed first at the hearing.

(e) **Evidence—(1) In general.** (i) The testimony of witnesses at a hearing shall be upon oath or affirmation and subject to cross-examination.

(ii) Any witness may, in the discretion of the examiner, be examined separately and apart from all other witnesses except those who may be parties to the proceeding.

(iii) The examiner shall exclude evidence which is immaterial, irrelevant, or unduly repetitious, or which is not of the sort upon which responsible persons are accustomed to rely.

(2) **Objections.** (i) If a party objects to the admission or rejection of any evidence or to the limitation of the scope of any examination or cross-examination, he shall state briefly the grounds of such objection, whereupon an automatic exception will follow if the objection is overruled by the examiner. The transcript shall not include argument or debate thereon except as ordered by the examiner. The

ruling of the examiner on any objection shall be a part of the transcript.

(ii) Only objections made before the examiner may subsequently be relied upon in the proceeding.

(3) **Depositions.** The deposition of any witness shall be admitted, in the manner provided in and subject to the provisions of § 123.11.

(4) **Affidavits.** Except as is otherwise provided in the rules in this part, affidavits may be admitted only if the evidence is otherwise admissible and the parties agree that affidavits may be used.

(5) **Proof of documents.** A true copy of every written entry in the records of the Department, made by an officer or employee thereof in the course of his official duty, and relevant to the issues involved in the hearing, shall be admissible as prima facie evidence of the facts stated therein, without the production of such officer or employee.

(6) **Exhibits.** Except where the examiner finds that the furnishing of copies is impracticable, a copy of each exhibit, in addition to the original, shall be filed with the examiner for the use of each other party to the proceeding. The examiner shall advise the parties as to the exact number of copies which will be required to be filed and shall make and have noted on the record the proper distribution of the copies.

(7) **Official notice.** Official notice will be taken of such matters as are judicially noticed by the courts of the United States and of any other matter of technical or scientific fact of established character: *Provided*, That the parties shall be given adequate notice, at the hearing or by reference in the examiner's report or tentative order or otherwise, of matters so noticed, and shall be given adequate opportunity to show that such facts are erroneously noticed.

(8) **Offer of proof.** Whenever evidence is excluded from the record, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof shall consist of a brief statement describing the evidence to be offered. If the evidence consists of a brief oral statement or of an exhibit, it shall be inserted into the transcript in toto. In such event, it shall be considered a part of the transcript if the Secretary decides that the examiner's ruling in excluding the evidence was erroneous. The examiner shall not allow the insertion of such evidence in toto if the taking of such evidence will consume a considerable length of time at the hearing. In the latter event, if the Sec-

retary decides that the examiner's ruling in excluding the evidence was erroneous, the hearing shall be reopened to permit the taking of such evidence.

(f) **Oral argument before examiner.** Oral argument before the examiner shall be allowed unless the examiner finds that the denial of such argument will not deprive the parties of an adequate opportunity for oral argument subsequently in the proceeding. Such argument may be limited by the examiner to any extent that he finds necessary for the expeditious disposition of the proceeding.

(g) **Transcript.** (1) During the period in which the proceeding has an active status in the Department, a copy of the transcript will be kept at the local office of the Branch nearest to the place where the respondent resides or has his principal place of business. If there are two or more respondents and they are located in different localities, the copy of the transcript shall be kept at the local office of the Branch nearest to the place where the hearing was held. This copy will be available for examination during official hours of business at the local office, but it shall remain the property of the Department and may not be removed from said office.

(2) Parties to the proceeding who desire a copy of the transcript of the hearing may place orders at the close of the hearing with the reporter, who will furnish and deliver such copies direct to the purchaser upon payment therefor at the rate per page provided by the contract between the reporter and the Department for such reporting service.

§ 123.11 Depositions—(a) **Application for taking deposition.** Upon the application of a party to the proceeding, the examiner, at any time after the filing of the order to show cause, may authorize under the facsimile signature of the Secretary, the taking of testimony by deposition. The application shall be in writing and shall be filed with the hearing clerk and shall set forth: (1) the name and address of the proposed deponent; (2) the name and address of the person (referred to hereinafter in this section as the "officer"), qualified under the rules in this part to take depositions, before whom the proposed examination is to be made; (3) the proposed time and place of the examination, which shall be at least 15 days after the date of the mailing of the application; and (4) the reasons why such deposition should be taken.

(b) **Examiner's authorization for taking deposition.** If the examiner is satisfied that good cause for taking the deposition is present, he may authorize its taking. The authorization shall be filed with the hearing clerk and shall be served upon the parties and shall state: (1) the time and place of the examination (which shall not be less than 10 days after the filing of the authorization); (2) the name of the officer before whom the examination is to be made; and (3) the name of the deponent. The officer and the time and place need not be the same as those suggested in the application.

(c) **Qualifications of officer.** The deposition shall be made before the examiner, or before an officer authorized by the law of the United States or by the law of the place of the examination to administer oaths, or before an officer authorized by the Secretary to administer oaths. No deposition shall be made before an officer who is a relative (within the third degree by blood or marriage), employee, attorney, or counsel of any party, or who is a relative (within the third degree by blood or marriage), or employee of any attorney or counsel for any party or who is financially interested in the result of the proceeding: *Provided, however*, That an officer who is an employee of the Department and is not a relative of any such party, attorney, or counsel may take depositions in any proceeding under the regulations.

(d) **Procedure on examination.** (1) The deponent shall be examined under oath or affirmation and shall be subject to cross-examination. The testimony of the deponent shall be recorded by the officer or by some person under his direction and in his presence. In lieu of oral cross-examination, parties may transmit written cross-interrogatories to the officer prior to the examination, and the officer shall propound such cross-interrogatories to the deponent.

(2) The applicant must arrange for the examination of the witness either by oral examination or by written interrogatories. If it is found by the examiner, upon the protest of a party to the proceeding, that such party has his residence and his place of business more than 100 miles from the place of the examination and that it would constitute an undue hardship upon such party to be represented at the examination, the applicant will be required to conduct the examination by means of interrogatories. When the examination is conducted by means of interrogatories, copies of the interrogatories shall be served upon the other parties to the pro-

ceeding at least five days prior to the date set for the examination, and the other parties shall be afforded an opportunity to file with the officer cross-interrogatories at any time prior to the time of the examination.

(e) **Signature by witness.** The transcript of the deposition shall be read to or by the deponent, unless such reading is waived by the parties and the deponent. Any changes which the deponent wishes to make shall be entered upon the deposition by the officer, with a statement of the reasons given by the deponent for such changes. The deposition shall be signed by the deponent, unless the parties by stipulation waive such signing, or unless the deponent is ill or cannot be found or refuses to sign. If the deponent does not sign, the officer shall sign and shall state on the record the reason why the deponent did not sign. In such case the deposition shall be as valid as though signed by the deponent, unless the examiner finds that the reason given by the deponent for his refusal to sign requires rejection of the deposition in whole or in part.

(f) **Certification by officer.** The officer shall certify on the deposition that the deponent was duly sworn by him and that the deposition is a true record of the deponent's testimony. He shall then securely seal the deposition, together with two copies thereof, in an envelope and mail the same by registered mail to the hearing clerk.

(g) **Use of depositions.** A deposition taken in accord with the provisions of this part, or in accord with the provisions of the rules of civil procedure of the courts of the United States, may be used in a proceeding under the rules in this part if the examiner finds that the evidence is otherwise admissible and (1) that the witness is dead; or (2) that the witness is at a greater distance than 100 miles from the place of hearing, unless it appears that the absence of the witness was procured by the party offering the deposition; or (3) that the witness is unable to attend or testify because of age, sickness, infirmity, or imprisonment; or (4) that the party offering the deposition has endeavored but has been unable to procure the attendance of the witness; or (5), in any event, upon application and notice that such exceptional circumstances exist as to make it desirable, in the interests of justice and with due regard to the importance of presenting the testimony orally before the examiner, to allow the deposition to be used. If any part of a deposition is put in evidence

by a party, any other party may require the production of the remainder, or any other portion, of the deposition.

§ 123.12 The examiner's report—(a) Filing the transcript of evidence. As soon as practicable after the close of the hearing, the reporter shall transmit to the hearing clerk the original of the transcript of the testimony and the original exhibits introduced in evidence at the hearing and as many copies of the transcript as may be required by the Branch. Upon receipt of the copies of the transcript, the Department will send a copy to the appropriate local office, as provided in § 123.10 (g), and will advise each party to the proceeding as to the date on which the transcript was filed with the hearing clerk. At the same time the reporter sends the transcript and copies thereof to the hearing clerk, he shall also transmit a copy of the transcript to each party who shall have filed an application therefor as provided in § 123.10 (g).

(b) **Proposed findings of fact, conclusions and order.** Within 10 days after receipt of notice that the transcript has been filed, each party may file with the hearing clerk proposed findings of fact, conclusions, and order, based solely on the record, and a brief in support thereof.

(c) **Examiner's report.** The examiner, within a reasonable time after the termination of the period allowed for the filing of proposed findings of fact, conclusions, and orders, and briefs in support thereof, shall prepare upon the basis of the record and shall file with the hearing clerk, his report, a copy of which shall be served upon each of the parties.

(d) **Exceptions.** Within 20 days after receipt of the examiner's report, the parties may file exceptions to the report. Any party who desires to take exceptions to any matter set out in the report shall transmit his exceptions in writing to the hearing clerk, referring to the relevant pages of the transcript, and suggesting a corrected finding of fact, conclusion, or order. Within the same period of time, each party shall transmit to the hearing clerk a brief statement in writing concerning each of the objections taken to the action of the examiner at the hearing, as set out in § 123.10, upon which the party wishes to rely, referring, where relevant, to the pages of the transcript. A party, if he files exceptions or a statement of objections, shall state in writing whether he desires to make an oral argument thereon before the Secretary; otherwise, he shall be deemed to have waived such oral argument.

§ 123.13 **The shortened procedure**—(a) **Consent of parties.** Whenever it appears to the examiner who is assigned to a proceeding that the proceeding can be more expeditiously handled under the informal procedure provided for in this section, he shall suggest to the parties that they consent to the use of such procedure. Except where oral hearing has been waived by failure to request it in proper time or otherwise, parties are free to consent to such procedure if they choose; declination of consent will not affect or prejudice the rights or interests of any party. A party, if he has not waived oral hearing, may consent to the use of the shortened procedure on the condition that the statements of fact be submitted in the form of depositions rather than affidavits. In such case, if the other parties agree, depositions shall be required to be filed in lieu of affidavits. If any party who has not waived oral hearing does not consent to the use of the shortened procedure, the proceeding will be set for oral hearing. The request that the shortened procedure be used need not originate with the examiner; any party may address a request to the examiner, asking that the shortened procedure be used. The examiner, in his suggestion to the parties, will set a short period of time in which the parties may indicate their consent to the shortened procedure; at the end of that period the examiner will notify the parties that the shortened procedure will or will not be used. All requests, suggestions, and notices mentioned in this section shall be filed with the hearing clerk.

(b) **Complainant's opening statement.** Within 20 days after receipt of notice that the shortened procedure will be used, the complainant shall file with the hearing clerk, in triplicate, in support of the order to show cause, an opening statement of the facts. A copy of such documents shall be served promptly by the hearing clerk upon the respondent.

(c) **Respondent's answering statement.** Within 20 days after receipt of the complainant's opening statement, the respondent may file with the hearing clerk, in triplicate, in support of his answer, an answering statement of the facts. A copy of the answering statement shall be served promptly by the hearing clerk upon the complaintant.

(d) **Complainant's statement in reply.** Within 10 days after receipt of the answering statement, the complainant may file with the hearing clerk, in triplicate, a statement in reply, which shall be confined strictly to replying to the facts and arguments set forth in the answering statement.

(e) **Contents of statements.** As used in this section, the term "statement" includes (1) statements of fact, signed and sworn to by persons having knowledge of those facts; (2) any documents filed as a part of the proof of the alleged facts (which documents shall be properly identified by verified statements in the statement filed or otherwise authenticated in such a manner that they would be admissible in evidence at an oral hearing under the rules of practice in this part); and (3) briefs containing arguments to sustain the contentions of the party submitting the statement. When practicable, the documents which constitute the record of any transaction in dispute should be made a part of the statement.

(f) **Verification.** Any facts stated in the statement must be sworn to (before a person legally authorized to administer oaths or before a person designated by the Secretary for the purpose) by a person who states in the affidavit that he has actual knowledge of the facts. Except under unusual circumstances, which shall be set forth in the affidavit, any such person shall be one who would appear as a witness if an oral hearing were held. The original of each document must show the signature, capacity, and impression seal (if the officer is required by law to have a seal) of the officer administering the oath and the date thereof. Copies must bear a notation that the original shows the data required in this respect. If a party elects to do so, he may file his statement of facts in the form of depositions rather than affidavits. Depositions filed under the shortened procedure, whether filed as a result of a requirement in the consent to the shortened procedure or voluntarily, shall conform to the provisions set forth in this section.

(g) **Stipulations.** In addition to or in lieu of such statements, the parties may file with the hearing clerk stipulations of facts signed by the parties or their representatives. Such stipulations shall become a part of the record. The stipulations must be filed with the hearing clerk within 20 days after notice that the shortened procedure will be used; or, if the complainant's opening statement is filed, within 20 days after the filing of such statement; or, if an answering statement is filed within 15 days after the filing thereof; or, if a statement in reply is filed, within 15 days after the filing thereof.

(h) **Waiver of right to file.** Failure to file, within the time prescribed, any statement or stipulation required or authorized under this section shall constitute a waiver of

the right to file such statement or stipulation. In such case, the examiner may prepare his report and the Secretary may make his final determination upon the evidence contained in the record at the time of such failure to file, except that no determination, other than dismissal of the proceeding, shall be made if the complainant fails to file an opening statement of the facts.

(i) **Examiner's report under the shortened procedure.** Except as otherwise may be directed by the examiner, the filing of the complainant's statement in reply will conclude the presentation of evidence. The examiner will thereupon file with the hearing clerk a notice that the partes may file proposed findings of fact, conclusions, and orders within 10 days after service of such notice. Upon the expiration of the period set for the filing of proposed findings, conclusions, and orders, the examiner will prepare his report, and the same procedure shall be followed thereafter as in proceedings where an oral hearing has been held.

(j) **Assignment for oral hearing.** At the request of any party or upon the examiner's own motion, the proceeding shall be set for oral hearing at any stage of the proceeding prior to the filing of the examiner's report: *Provided*, That, where the party making such request has waived oral hearing by failure to request it in proper time, it is provided in § 123.10, the assignment for oral hearing shall be in the discretion of the examiner.

§ 123.14 Transmittal of record. The hearing clerk, immediately following the period allowed for the filing of exceptions, shall transmit to the Secretary the record of the proceeding. Such record shall include: the pleadings; motions and requests filed, and rulings thereon; the transcript of the testimony taken at the hearing, together with the exhibits filed therein; any statements filed under the shortened procedure; any documents or papers filed in connection with prehearing conferences; such proposed findings of fact, conclusions, and orders, and briefs in support thereof, as may have been filed in connection with the hearing; the examiner's report; and such exceptions, statements of objections, and briefs in support thereof as may have been filed in the proceeding.

§ 123.15 Argument before Secretary—(a) **Oral argument.** Unless a party has included in his exceptions a request for oral argument before the Secretary or has filed a separate request for oral argument prior to the expiration

of the last date for filing such exceptions, he shall be deemed to have waived his right to such oral argument.

(b) **Briefs.** The parties may file written briefs either in addition to oral argument or in lieu thereof.

(c) **Scope of argument.** Except where the Secretary determines that argument on additional issues would be helpful, argument, whether oral or on brief, shall be limited to the issues raised by the exceptions and statement of objections. If the Secretary determines that additional issues should be argued, counsel for the parties shall be given reasonable notice of such determination, so as to permit preparation of adequate argument on all the issues to be argued.

§ 123.16 Preparation and issuance of order—(a) **Preparation of order.** As soon as practicable after the receipt of the record from the hearing clerk, or, in case oral argument was had, as soon as practicable thereafter, the Secretary, upon the basis of and after due consideration of the record, shall prepare his order in the proceeding which shall include findings, conclusions, order, and rulings on motions, exceptions, statements of objections, and proposed findings, conclusions, and orders submitted by the parties not theretofore ruled upon. If an oral argument was held, the order shall be prepared by and shall be issued over the signature of the official who heard such oral argument, unless the parties shall consent to a different arrangement. At no stage of the proceeding between its institution and the issuance of the order shall the Secretary discuss ex parte the merits of the proceeding with any person who is connected with the proceeding in an advocative or in an investigative capacity, or with any representative of such person: *Provided*, That the Secretary may discuss the merits of the case with such a person if all parties to the proceedings, or their representatives, have been given an opportunity to be present. Any memorandum or other communication addressed to the Secretary, during the pendency of the proceeding, and relating to the merits thereof, by, or on behalf of, any party shall be regarded as argument made in the proceeding and shall be filed with the hearing clerk, who shall serve a copy thereof upon the opposite party to the proceeding, and opportunity will be given the opposite party to file a reply thereto.

(b) **Issuance of order.** The order, prepared as described in paragraph (a) of this section, shall be issued and served

upon the parties as the final order in the proceeding without further procedure: *Provided*, That, if the terms of the order differ substantially from those purported in the report of the examiner, the Secretary may, if he deems it advisable to do so, direct that a copy of the order be served upon the parties as a tentative order; and, in such event, opportunity shall be given the parties to file exceptions thereto and written arguments or briefs in support of such exceptions. In such case, if no exceptions are filed within 20 days following the service of the tentative order, it shall be issued and served as the final order in the proceeding.

§ 123.17 Applications for reopening hearings; for rehearings or reargument of proceedings; or for reconsideration of orders—(a) Petition requisite—(1) Filing; service. An application for reopening the hearing to take further evidence, or for rehearing or reargument of the proceeding, or for reconsideration of the order, must be made by petition to the Secretary filed with the hearing clerk, who immediately shall notify and serve a copy thereof upon the other party to the proceeding. Every such petition must state specifically the grounds relied upon.

(2) **Petitions to reopen hearings.** A petition to reopen a hearing to take further evidence may be filed at any time prior to the issuance of the final order. Every such petition shall state briefly the nature and purpose of the evidence to be adduced, shall show that such evidence is not merely cumulative, and shall set forth a good reason why such evidence was not adduced at the hearing. Every such petition shall be served by the hearing clerk on the other parties to the proceeding.

(3) **Petitions to rehear or reargue proceedings or to reconsider orders.** A petition to rehear or reargue the proceeding or to reconsider the order must be filed within 15 days after the date of the service of the order. Every such petition must state specifically the matters claimed to have been erroneously decided and alleged errors must be briefly stated.

(b) **Procedure for disposition of petitions.** Within 20 days following the service of any petition provided for in this section, the other party to the proceeding shall file with the hearing clerk an answer thereto. As soon as practicable thereafter, the Secretary shall announce his decision whether to grant or to deny the petition. Unless the Secretary shall determine otherwise, operation of the order shall not be

stayed pending the decision to grant or to deny the petition. In the event that any such petition is granted by the Secretary, the applicable rules of practice, as set out elsewhere herein, shall be followed. A person filing a petition under this section shall be regarded as the complainant, although he shall be referred to as the complainant or respondent, depending upon his designation in the original proceeding.

§ 123.18 Hearings before Secretary. The Secretary may act in the place and stead of an examiner in any proceeding hereunder. When he so acts, the hearing clerk shall transmit the record to the Secretary at the expiration of the period provided for the filing of proposed findings of fact, conclusions, and orders, and the Secretary shall thereupon, after due consideration of the record, issue his final order in the proceeding: *Provided*, That he may issue a tentative order, in which event the parties shall be afforded an opportunity to file exceptions before the issuance of the final order.

§ 123.19 Filing; service; extensions of time; additional time for filing; and computation of time—(a) **Filing; number of copies.** Except as is provided otherwise herein, all documents or papers required or authorized by the rules in this part to be filed with the hearing clerk shall be filed in duplicate: *Provided*, That, where there are more than two parties to the proceeding, a sufficient number of copies shall be filed so as to provide for service upon all the parties to the proceeding. Any document or paper, required or authorized under the rules in this part to be filed with the hearing clerk, shall, during the course of an oral hearing, be filed with the examiner.

(b) **Service; proof of service.** Copies of all such documents or papers shall be served upon the parties by the hearing clerk, by the examiner, or by some other employee of the Department, or by a United States Marshal or his deputy. Service shall be made either (1) by delivering a copy of the document or paper to the individual to be served or to a member of the partnership to be served or to the president, secretary, or other executive officer or any director of the corporation, organization, or association to be served, or to the attorney or agent of record of such individual, partnership, corporation, organization, or association; or (2) by leaving a copy of the document or paper at the principal office or place of business of such individual, partnership, corporation, organization, or association, or of his or its attorney or agent of record; or (3) by registering and mail-

ing a copy of the document or paper, addressed to such individual, partnership, corporation, organization, or association, or to his or its attorney or agent of record, at his or its last known residence or principal office or place of business. Proof of service hereunder shall be made by the affidavit of the person who actually made the service: *Provided*, That, if the service be made by registered mail, as outlined in (3) above, proof of service shall be made by the return post-office receipt. The affidavit and post-office receipt contemplated herein shall be filed with the hearing clerk, and the fact of filing thereof shall be noted on the docket of the proceeding.

(c) **Extensions of time.** The time for the filing of any document or paper required or authorized under the rules in this part to be filed may be extended by the examiner (before the examiner's report is filed) or by the Secretary (after the examiner's report is filed), if request for such extension of time is made prior to or on the final date allowed for such filing, and if, in the judgment of the examiner or the Secretary, as the case may be, after notice to and consideration of the views of the other party, there is good reason for the extension.

(d) **Effective date of filing.** Any document or paper required or authorized under the rules in this part to be filed shall be deemed to be filed at the time when it reaches the Department of Agriculture in Washington, D. C.

(e) **Additional time for filing.** The time for the filing of any document or paper required or authorized under the rules in this part to be filed shall be five days longer when the party resides or has his or its principal place of business at any place west of 104° west longitude.

(f) **Computation of time.** Sundays and holidays shall be included in computing the time allowed for the filing of any document or paper: *Provided*, That, when such time expires on a Sunday or legal holiday, such period shall be extended to include the next following business day.

○